Please type a plus sign (+) inside this box [+]

PTO/SB/05 (12/97)
Approved for use through 09/30/00. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b)

Attorney Docket No. 002933.P001C Total Pages 5

First Named Inventor or Application Identifier Thomas C. Kuracina, et al.

Express Mail Label No. EL034163855US

ADDRESS TO: **Assistant Commissioner for Patents**
Box Patent Application
Washington, D. C. 20231

APPLICATION ELEMENTS
See MPEP chapter 600 concerning utility patent application contents.

1. X Fee Transmittal Form
(Submit an original, and a duplicate for fee processing)

2. X Specification (Total Pages 117)
(preferred arrangement set forth below)
- Descriptive Title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings (if filed)
- Detailed Description
- Claims
- Abstract of the Disclosure

3. X Drawings(s) (35 USC 113) (Total Sheets 38)

4. X Oath or Declaration (Total Pages 5) Signed

a. ___ Newly Executed (Original or Copy)

b. X Copy from a Prior Application (37 CFR 1.63(d))
(for Continuation/Divisional with Box 17 completed) **(Note Box 5 below)**

i. ___ DELETIONS OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

5. X Incorporation By Reference (useable if Box 4b is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ___ Microfiche Computer Program (Appendix)

7. ___ Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. ___ Computer Readable Copy
b. ___ Paper Copy (identical to computer copy)
c. ___ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. __ Assignment Papers (cover sheet & documents(s))
9. __ a. 37 CFR 3.73(b) Statement (where there is an assignee)
__ b. Power of Attorney
10. __ English Translation Document (if applicable)
11. X a. Information Disclosure Statement (IDS)/PTO-1449
X b. Copies of IDS Citations (front page only)
12. X Preliminary Amendment
13. X Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
14. ____a. Small Entity Statement(s)
X b. Statement filed in prior application, Status still proper and desired
15. ____ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. X Other: Postcard and Certificate of Express Mailing

17. **If a CONTINUING APPLICATION,** check appropriate box and supply the requisite information:
X Continuation ____ Divisional ____ Continuation-in-part (CIP)
of prior application No: 08/807,328

18. **Correspondence Address**
____ Customer Number or Bar Code Label _____ (Insert Customer No. or Attach Bar Code Label here)
or
X Correspondence Address Below

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PTO/SB/17(10/96)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL

TOTAL AMOUNT OF PAYMENT ($) 1795.00

Complete if Known:
Application No. Not Yet Assigned
Filing Date Herewith
First Named Inventor Thomas C. Kuracina ,et al.
Group Art Unit Not Yet Assigned
Examiner Name Not Yet Assigned
Attorney Docket No. 002933.P001C

METHOD OF PAYMENT (check one)

1. [ ] **The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:**

   Deposit Account Number 02-2666
   Deposit Account Name _____

   [X] **Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17**

   [ ] **Charge the Issue Fee Set in 37 CFR 1.18 at the Mailing of the Notice of Allowance, 37 CFR 1.131(b)**

2. X **Payment Enclosed**
   X **Check**
   _____ **Money Order**
   _____ **Other**

FEE CALCULATION (fees effective 10/01/97)

1. **FILING FEE**

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	790	201	395	Utility application filing fee	395.00
106	330	206	165	Design application filing fee	
107	540	207	270	Plant filing fee	
108	790	208	395	Reissue filing fee	
114	150	214	75	Provisional application filing fee	

SUBTOTAL (1) $ 395.00

2. **CLAIMS**

			Extra	Fee from below		Fee Paid
Total Claims	135	– 20 =	115	11.00	=	1265.00
Independent Claims	3	– 3 =	0	41.00	=	0.00
Multiple Dependent Claims			3	135.00	=	135.00

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
103	22	203	11	Claims in excess of twenty	1265.00
102	82	202	41	Independent claims in excess of 3	0
104	270	204	135	Multiple dependent claim	135.00
109	82	209	41	Reissue independent claims over original patent	
110	22	210	11	Reissue claims in excess of 20 and over original patent	

SUBTOTAL (2) $1400.00

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for response within first month	
116	400	216	200	Extension for response within second month	
117	950	217	475	Extension for response within third month	
118	1,510	218	755	Extension for response within fourth month	
128	2,060	228	1,030	Extension for response within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive unavoidably abandoned application	
141	1,320	241	660	Petition to revive unintentionally abandoned application	
142	1,320	242	660	Utility issue fee (or reissue)	
143	450	243	225	Design issue fee	
144	670	244	335	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	240	126	240	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	790	246	395	For filing a submission after final rejection (see 37 CFR 1.129(a))	
149	790	249	395	For each additional invention to be examined (see 37 CFR 1.129(a))	

Other fee (specify) _____

Other fee (specify) _____

SUBTOTAL (3)$_____

*Reduced by Basic Filing Fee Paid

SUBMITTED BY:

Typed or Printed Name: Tim L. Kitchen

Signature Tim L Kitchen Date 9/31/98

Reg. Number 41,900 Deposit Account User ID_____
(complete if applicable)

PTO/SB/17 (10-96)
Approved for use through 09/30/98 OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

EXPRESS MAIL CERTIFICATE OF MAILING

"Express Mail" mailing label number: EL034163855US
Date of Deposit: August 31, 1998
I hereby certify that I am causing this paper or fee to be deposited with the United States Postal Service "Express Mail Post Office to Addressee" service on the date indicated above and that this paper or fee has been addressed to the Assistant Commissioner for Patents, Washington, D. C. 20231

SHERRI L. QUATTRIN
(Typed or printed name of person mailing paper or fee)

Sherri L Quattrin
(Signature of person mailing paper or fee)

8-31-98
(Date signed)

Appln. No. *** Filing Date Herewith BSTZ Docket# 002933.P001C Atty/Secy TLK/slq
Date Mailed 8/31/98 Docket Due Date *** Client INJECTIMED, INC.
Title NEEDLE TIP GUARD FOR HYPODERMIC NEEDLES
Inventor(s) Kuracina, Ohnemus, Smith, Cohen

The following has been received in the U.S. Patent & Trademark Office on the date stamped hereon:

- ☐ Amendment/Response (___ pgs)
- ☐ Amendment/Response After Final (___ pgs)
- ☐ Appeal Brief & two copies (___ pgs each)
- ☐ Application - Rule 1.53 Utility (___ pgs)
- ☒ Application - Rule 1.53 Cont. (117 pgs)
- ☐ Application - Rule 1.60 _____ (___ pgs)
- ☐ Application - Rule 1.62 _____ (___ pgs)
- ☐ Application - Design (___ pgs)
- ☐ Application - PCT (___ pgs)
- ☐ Assignment & Cov. _____
- ☒ Certificate of Mailing
- ☒ Express Mail No. EL034163855US
- ☒ Declaration & POA *Signed* (5 pgs)
- ☐ Disclosure Docs & Inv's Signed Ltr
- ☒ Drawings: 38 sheets, 148 figures
- ☒ Information Disclosure Statement & PTO-1449 (13 pgs)
- ☐ Issue Fee Transmittal
- ☐ Notice of Appeal
- ☐ Petition for Extension of Time: _____ (___ pgs)
- ☐ Petition for: _____ (___ pgs)
- ☐ Power of Attorney (___ pgs)
- ☒ Preliminary Amendment (19 pgs)
- ☐ Reply Brief (___ pgs)
- ☐ Response to Notice of Missing Parts (___ pgs)
- ☐ Small Entity Declaration for Indep. Inven/Sm. Business
- ☐ Transmittal Letter (original & copy)
- ☒ Other First page of all cited artwork

☒ Check No. 24050 Amount $1,795.00
☐ Check No. _____ Amount _____
☐ Check No. _____ Amount _____

v. 3.3.4

Attorney Docket No. 02933.P001C

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kuracina, et al.

Serial No.: Not Yet Assigned

Filing Date: Herewith

For: NEEDLE TIP GUARD FOR HYPODERMIC NEEDLES

Examiner: Not Yet Assigned

Art Unit: Not Yet Assigned

which is a continuation of:

Serial No. 08/807,328
Filed February 27, 1997

"Express Mail" mailing label number: EL034163855US
Date of Deposit: August 31 1998
I hereby certify that I am causing this paper or fee to be deposited with the United States Postal Service "Express Mail Post Office to Addressee" service on the date indicated above and that this paper or fee has been addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231
SHERRI L. QUATTRIN
(Typed or printed name of person mailing paper or fee)
Sherri L. Quattrin
(Signature of person mailing paper or fee)
8-31-98
(Date signed)

Preliminary Amendment

Assistant Commissioner of
Patent & Trademarks
Washington, D.C. 20231

Dear Sir:

Prior to the examination of the above-referenced patent application, please enter the following amendments.

IN THE SPECIFICATION

Prior to the first sentence on the first page of the specification please add the following sentence: -- This is a continuation of application no. 08/807,328, filed February 27, 1997.--

IN THE CLAIMS

Please cancel claims 46-93 without prejudice.

Please amend the claims as follows:

1. (Amended) A needle protective device comprising:

a needle guard slidably mounted on a needle having a sharpened distal end, said needle guard having a proximal end and a distal end, said needle guard containing a non-metal movable needle trap that is biased toward said needle, said needle trap

entrapping said sharpened distal end of said needle when said distal end of said needle guard moves near said sharpened distal end of said needle[; and].

[limiting means for limiting the forward movement of said needle guard along said needle.]

26. (Amended) The [assembly] device of claim 7 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

27. (Amended) The [assembly] device of claim 26 wherein said needle trap comprises a lead-in section having a second notch, said lead-in section locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

28. (Amended) The [assembly] device of claim 26 wherein said needle trap comprises a lead-in section having a multilevel landing, said lead-in section locating said resilient member within said first notch and said landing, said landing releasably retaining said distal end of said resilient member.

29. (Amended) The [assembly] device of claim 7 wherein said needle trap comprises at least one longitudinal channel for reducing the contact surface area between said needle trap and said resilient member.

30. (Amended) The [assembly] device of claim 8 [wherein said limiting means comprises] further comprising a tether having a first end and a second end, said first end attached to said housing, said second end attached to said needle guard.

31. (Amended) The [assembly] device of claim 21 [wherein said limiting means comprises] further comprising a tether having a first end and a second end, said first end attached to said hub, said second end attached to said needle guard.

32. (Amended) The [assembly] device of claim 30 or 31 wherein said tether is flexible.

33. (Amended) The [assembly] device of claim 8 [wherein said limiting means comprises] further comprising a rigid tether and said housing includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said housing aperture, said second end attached to said needle guard.

34. (Amended) The [assembly] device of claim 21 [wherein said limiting means comprises] further comprising a rigid tether and said hub includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from

advancing through said hub aperture, said second end attached to said needle guard.

35. (Amended) The [assembly] device of claim 32 wherein said hub includes a pocket for storing said flexible tether.

36. (Amended) The [assembly] device of claim 1 wherein said needle includes a change in contour near the sharpened distal end of said needle, said change in contour providing [said] limiting means to limit the forward movement of said needle guard along said needle.

37. (Amended) The [assembly] device of claim 8 wherein said housing comprises at least one projection for removably attaching a protective storage cover to said housing.

38. (Amended) The [assembly] device of claim 21 wherein said hub comprises at least one projection for removably attaching a protective storage cover to said hub.

39. (Amended) The [assembly] device of claim 1 wherein said needle guard is side-loadable onto said needle.

40. (Amended) The [assembly] device of claim 1 wherein said needle guard comprises a first section and a second section, said first and second sections having attachable mating faces.

41. (Amended) The [assembly] device of claim 40 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

42. (Amended) The [assembly] device of claim 39 wherein said needle guard includes a longitudinal recess for receiving said needle.

43. (Amended) The [assembly] device of claim 7 further comprising a shroud for containing said resilient member and said needle guard.

44. (Amended) The [assembly] device of claim [46] 43 wherein said shroud comprises a collapsible bellows.

45. (Amended) The [assembly] device of claim 7 further comprising a shroud for containing said needle guard and said needle when the sharpened distal end of said needle is contained within said needle guard, said shroud comprising a bellows, said bellows providing [the] limiting means to limit the forward movement of said needle guard along said needle.

Please add the following new claims:

94. (New) The device of claim 1 wherein said needle guard comprises a first section and a second section, said first and second sections being attachable over said needle.

95. (New) The device of claim 94 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

96. (New) A needle protective device comprising:

a needle guard slidably mounted on a needle having a sharpened distal end, said needle guard having a proximal end and a distal end, said needle guard containing a movable needle trap integral to said needle guard that is biased toward said needle, said needle trap entrapping said sharpened distal end of said needle when said distal end of said needle guard moves near said sharpened distal end of said needle.

97. (New) The device of claim 96 wherein said needle trap is inherently biased toward said needle.

98. (New) The device of claim 96 further comprising biasing means for urging said needle guard forward toward said sharpened distal end of said needle.

99. (New) The device of claim 98 further comprising retaining means for releasably retaining said needle guard near the base of said needle.

100. (New) The device of claim 99 further comprising triggering means for releasing said retaining means.

101. (New) The device of claim 98 wherein said biasing means comprises a resilient member having a proximal end and a distal end.

102. (New) The device of claim 98 wherein the base of said needle is coupled to a housing having a forward end, said needle extending axially from said forward end of said housing.

103. (New) The device of claim 102 wherein said resilient member is disposed between said housing and said needle guard.

104. (New) The device of claim 103 wherein said resilient member comprises a coil spring.

105. (New) The device of claim 99 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said housing, said distal end of said latching arm comprising a protrusion.

106. (New) The device of claim 105 wherein said needle guard includes a recess for receiving said protrusion.

107. (New) The device of claim 105 wherein said latching arm further comprises a finger pad for manually disengaging said latching arm from said needle guard.

108. (New) The device of claim 105 wherein said latching arm comprises a ramp for biasing said latching arm in an outward manner when a compressive force is applied to said needle guard.

109. (New) The device of claim 103 wherein said forward end of said housing comprises an opening, the base of said needle being secured within said opening.

110. (New) The device of claim 109 wherein said housing comprises a longitudinal wall section extending forward from said housing, said wall section substantially surrounding said opening.

111. (New) The device of claim 110 wherein said wall section comprises at least one aperture for providing access to said opening.

112. (New) The device of claim 110 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard including a recess for receiving said protrusion.

113. (New) The device of claim 112 wherein said triggering means comprises a finger pad positioned on said latching arm for manually disengaging said latching arm from said needle guard.

114. (New) The device of claim 112 wherein said triggering means comprises a ramp positioned on said latching arm for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

115. (New) The device of claim 102 further comprising a needle guard hub coupled to said housing, said hub having a longitudinal wall section extending

forward from said hub, said resilient member disposed between said hub and said needle guard.

116. (New) The device of claim 115 wherein said wall section comprises an aperture for accessing said needle.

117. (New) The device of claim 115 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard having a recess for receiving said protrusion.

118. (New) The device of claim 117 wherein said triggering means comprises a finger pad on said latching arm for manually disengaging said latching arm from said needle guard.

119. (New) The device of claim 117 wherein said triggering means comprises a ramp for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

120. (New) The device of claim 101 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

121. (New) The device of claim 120 wherein said needle trap comprises a lead-in section having a second notch, said lead-in section locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

122. (New) The device of claim 120 wherein said needle trap comprises a lead-in section having a multilevel landing, said lead-in section locating said resilient member within said first notch and said landing, said landing releasably retaining said distal end of said resilient member.

123. (New) The device of claim 101 wherein said needle trap comprises at least one longitudinal channel for reducing the contact surface area between said needle trap and said resilient member.

124. (New) The device of claim 102 further comprising a tether having a first end and a second end, said first end attached to said housing, said second end attached to said needle guard.

125. (New) The device of claim 115 further comprising a tether having a first end and a second end, said first end attached to said hub, said second end attached to said needle guard.

126. (New) The device of claim 124 or 125 wherein said tether is flexible.

127. (New) The device of claim 102 further comprising a rigid tether and said housing including an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said housing aperture, said second end attached to said needle guard.

128. (New) The device of claim 115 further comprising a rigid tether and said hub includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said hub aperture, said second end attached to said needle guard.

129. (New) The device of claim 126 wherein said hub includes a pocket for storing said flexible tether.

130. (New) The device of claim 96 wherein said needle includes a change in contour near the sharpened distal end of said needle, said change in contour providing limiting means to limit the forward movement of said needle guard along said needle.

131. (New) The device of claim 102 wherein said housing comprises at least one projection for removably attaching a protective storage cover to said housing.

132. (New) The device of claim 115 wherein said hub comprises at least one projection for removably attaching a protective storage cover to said hub.

133. (New) The device of claim 96 wherein said needle guard is side-loadable onto said needle.

134. (New) The device of claim 96 wherein said needle guard comprises a first section and a second section, said first and second sections being attachable over said needle.

135. (New) The device of claim 134 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

136. (New) The device of claim 133 wherein said needle guard includes a longitudinal recess for receiving said needle.

137. (New) The device of claim 101 further comprising a shroud for containing said resilient member and said needle guard.

138. (New) The device of claim 101 further comprising a shroud for containing said needle guard and said needle when the sharpened distal end of said needle is contained within said needle guard, said shroud comprising a bellows, said bellows providing limiting means to limit the forward movement of said needle guard along said needle.

139. (New) A needle protective device comprising:

a needle guard slidably mounted on a needle having a sharpened distal end, said needle guard having a first section, a second section, a proximal end and a distal end, said first and second sections being attachable over said needle, said needle guard containing a movable needle trap that is biased toward said needle, said needle trap entrapping said sharpened distal end of said needle when said distal end of said needle guard moves near said sharpened distal end of said needle.

140. (New) The device of claim 139 wherein said needle trap is integral to said needle guard.

141. (New) The device of claim 139 wherein said needle trap is inherently biased toward said needle.

142. (New) The device of claim 139 further comprising biasing means for urging said needle guard forward toward said sharpened distal end of said needle.

143. (New) The device of claim 142 further comprising retaining means for releasably retaining said needle guard near the base of said needle.

144. (New) The device of claim 143 further comprising triggering means for releasing said retaining means.

145. (New) The device of claim 142 wherein said biasing means comprises a resilient member having a proximal end and a distal end.

146. (New) The device of claim 142 wherein the base of said needle is coupled to a housing having a forward end, said needle extending axially from said forward end of said housing.

147. (New) The device of claim 146 wherein said resilient member is disposed between said housing and said needle guard.

148. (New) The device of claim 147 wherein said resilient member comprises a coil spring.

149. (New) The device of claim 143 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said housing, said distal end of said latching arm comprising a protrusion.

150. (New) The device of claim 149 wherein said needle guard includes a recess for receiving said protrusion.

151. (New) The device of claim 149 wherein said latching arm further comprises a finger pad for manually disengaging said latching arm from said needle guard.

152. (New) The device of claim 149 wherein said latching arm comprises a ramp for biasing said latching arm in an outward manner when a compressive force is applied to said needle guard.

153. (New) The device of claim 147 wherein said forward end of said housing comprises an opening, the base of said needle being secured within said opening.

154. (New) The device of claim 153 wherein said housing comprises a longitudinal wall section extending forward from said housing, said wall section substantially surrounding said opening.

155. (New) The device of claim 154 wherein said wall section comprises at least one aperture for providing access to said opening.

156. (New) The device of claim 154 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard including a recess for receiving said protrusion.

157. (New) The device of claim 156 wherein said triggering means comprises a finger pad positioned on said latching arm for manually disengaging said latching arm from said needle guard.

158. (New) The device of claim 156 wherein said triggering means comprises a ramp positioned on said latching arm for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

159. (New) The device of claim 146 further comprising a needle guard hub coupled to said housing, said hub having a longitudinal wall section extending forward from said hub, said resilient member disposed between said hub and said needle guard.

160. (New) The device of claim 159 wherein said wall section comprises an aperture for accessing said needle.

161. (New) The device of claim 159 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard having a recess for receiving said protrusion..

162. (New) The device of claim 161 wherein said triggering means comprises a finger pad on said latching arm for manually disengaging said latching arm from said needle guard.

163. (New) The device of claim 161 wherein said triggering means comprises a ramp for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

164. (New) The device of claim 145 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

165. (New) The device of claim 164 wherein said needle trap comprises a lead-in section having a second notch, said lead-in section locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

166. (New) The device of claim 164 wherein said needle trap comprises a lead-in section having a multilevel landing, said lead-in section locating said resilient member within said first notch and said landing, said landing releasably retaining said distal end of said resilient member.

167. (New) The device of claim 145 wherein said needle trap comprises at least one longitudinal channel for reducing the contact surface area between said needle trap and said resilient member.

168. (New) The device of claim 146 further comprising a tether having a first end and a second end, said first end attached to said housing, said second end attached to said needle guard.

169. (New) The device of claim 159 further comprising a tether having a first end and a second end, said first end attached to said hub, said second end attached to said needle guard.

170. (New) The device of claim 168 or 169 wherein said tether is flexible.

171. (New) The device of claim 146 further comprising a rigid tether and said housing includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said housing aperture, said second end attached to said needle guard.

172. (New) The device of claim 159 further comprising a rigid tether and said hub includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said hub aperture, said second end attached to said needle guard.

173. (New) The device of claim 170 wherein said hub includes a pocket for storing said flexible tether.

174. (New) The device of claim 139 wherein said needle includes a change in contour near the sharpened distal end of said needle, said change in contour

providing limiting means to limit the forward movement of said needle guard along said needle.

175. (New) The device of claim 146 wherein said housing comprises at least one projection for removably attaching a protective storage cover to said housing.

176. (New) The device of claim 159 wherein said hub comprises at least one projection for removably attaching a protective storage cover to said hub.

177. (New) The device of claim 139 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

178. (New) The device of claim 145 further comprising a shroud for containing said resilient member and said needle guard.

179. (New) The device of claim 145 further comprising a shroud for containing said needle guard and said needle when the sharpened distal end of said needle is contained within said needle guard, said shroud comprising a bellows, said bellows providing limiting means to limit the forward movement of said needle guard along said needle.

180. (New) The device of claim 1 wherein said needle trap is made of a plastic material.

Remarks

Applicant respectfully requests that this amendment be entered prior to the examination of the above-referenced patent application. Claims 46-93 have been canceled. Claims 1 and 26-45 have been amended. New claims 94-180 have been added. No new matter has been added.

Please charge any shortages and credit any overcharges to Deposit Account No. 02-2666.

Respectfully submitted,

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NEEDLE TIP GUARD FOR HYPODERMIC NEEDLES

RELATED APPLICATIONS

This application is related to and claims the benefit of filing dates of the following United States Provisional Patent Applications: (1) Serial No. 60/012,343, entitled PROTECTED HYPODERMIC NEEDLE WITH AUTOMATIC AND MANUAL COVERING MEANS, filed February 27, 1996; (2) Serial No. 60/025,273, entitled HYPODERMIC DEVICES WITH SAFETY FEATURES, filed September 12, 1996; and (3) Serial No. 60/031,399, entitled HYPODERMIC DEVICES WITH IMPROVED SAFETY FEATURES, filed November 19, 1996.

FIELD OF THE INVENTION

The present invention relates generally to needle tip guards for hypodermic needles.

BACKGROUND OF THE INVENTION

The advent of Human Immunodeficiency Virus (HIV), combined with the increasing incidence of other bloodborne pathogens such as Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV), present healthcare workers with an occupational hazard unprecedented in modern medicine. The risk of contracting HIV from a needlestick injury is approximately 1 in 250, but for those who contract HIV infection as a result of a needlestick injury the risk becomes 1 in 1. The risk of contracting the more contagious HBV as a result of a needlestick injury ranges from 1 in 6 to 1 in 30.

There are also over twenty more known bloodborne pathogens which are transmitted via blood and bodily fluids. The presence of any of these pathogens in patients poses a risk to healthcare workers when invasive procedures are performed. Infectious diseases are now the third leading cause of death, behind heart disease and cancer, signifying a growing need for safer hypodermic equipment. Ten years ago, infectious diseases were classified as the fifth leading cause of death, they are now ranked third. This increase of infectious disease is attributed mainly to the over-use of antibiotics and the growing availability of re-usable, hollow-bore hypodermic equipment.

As the population of infected individuals increases, more people will be treated by healthcare workers, further increasing the odds of disease transmission from patient to healthcare worker. Also, the use of disposable hypodermic equipment is increasing at approximately 7% per annum. Additionally, a meaningful number of clusters of patient to patient transmission in the healthcare setting has been identified throughout the world. Early data suggests improper infection control techniques contribute directly to this increase: including improper use of hypodermic equipment, multiple-dose medicine vials; and failure to change protective gloves and gear for each new patient.

Recent studies also cite the discovery of significant blood contamination on re-usable blood collection vacuum tube holders which are routinely used to collect blood from different patients. Common practice is to ship one vacuum tube holder with 100 blood collection needles. It is likely that new routes of disease

transmission will also be found in the future. Healthcare workers are increasingly at risk to disease transmission and nurses perform the majority of invasive hypodermic procedures, such as injecting medicine, collecting blood and inserting indwelling intravenous (I.V.) catheters. Nurses and other healthcare personnel are routinely injured by the exposed, sharp lancet of the needle after use on a patient. The critical time where a percutaneous injury can occur is from the moment the needle is withdrawn from the patient, or I.V. port, to the time the contaminated needle is safety discarded.

There are approximately 5.6 million workers in the United States (U.S.) whose jobs place them at risk for sustaining an accidental needlestick injury. Medical literature cites approximately one million reported needlestick accidents occur in the U.S. each year, with an additional two-thirds believed to be unreported. One million injuries per year translates to a needlestick injury, on average, every thirty-two seconds. Prior to the proliferation of HIV and serum hepatitis, a needlestick injury was considered a routine part of providing patient care. A needlestick injury now carries a life-threatening consequence and healthcare workers must live with this terror on a daily basis.

Hypodermic needles are used in a wide variety of invasive medical procedures with approximately 12 billion units being consumed on an annual basis. Basically, the great majority of hypodermic needles are intended for a single-use on an individual patient and are provided sterile in a variety of lengths and gauges. Hypodermic needles are normally discarded after a single use into a specially designed, puncture-proof biohazard container.

Hypodermic needles are used in medicine, science, veterinary medicine, the biotechnology and pharmaceutical industries, and also in the chemical industry. Medical and veterinary uses range from injecting medication or diluent into a patient or I.V. port, collecting blood, bodily fluids or specimens from patients and, preparing medication. The biotechnology and pharmaceutical applications mainly involve research where substances, liquids, gases or compounds are injected, mixed or withdrawn through a membrane or barrier into a specimen or controlled field. Chemical industry applications involve injecting or removing substances, liquids, gases or compounds to or from a specimen or controlled field. In each and every instance, whether medical or industrial, exposed needles pose a danger of injuring the user.

In medicine, in addition to the danger of contacting contaminated blood or bodily fluids, highly reactive or toxic substances are used for chemotherapy or therapeutic purposes. In the biotechnology, pharmaceutical and chemical industries, toxic, highly reactive, corrosive materials or substances are combined or withdrawn from a variety of experiments or projects.

Despite all the obvious dangers associated with the use of exposed hypodermics, and the availability of manually activated safety hypodermic devices, unguarded, exposed hypodermic needles still dominate the marketplace. This is due to the common practice in the industry where exposed hypodermic needles are sold at discounted prices and usually come packaged with other medical equipment and supplies. Medical institutions continue to purchase exposed hypodermics in this fashion simply for economic reasons.

The basic problem with many of the present day safety hypodermic devices is that they are meant to be manually activated, or in the language of the medical device industry, they are considered "active" devices. They may have safety shields, retractable needles, moveable sheaths or the like; but they generally require the user to complete another procedure to facilitate engagement of the safety mechanism. Although there are a number of retractable needle into syringe devices available, the manufacturing costs associated with these devices are prohibitively high.

What is needed is a low-cost safety hypodermic apparatus with a universal application.

SUMMARY OF THE INVENTION

It is therefore an object of this invention to provide a needle point guard that effectively shields the sharpened distal tip of the needle after use.

It is another object of this invention to provide a safety hypodermic apparatus which is automatic and/or semi-automatic covering, fail-safe and single-use in nature.

It is another object of this invention to provide a safety hypodermic apparatus which looks similar to a standard, exposed, disposable hypodermic needled device (i.e., the needle and needle tip are exposed prior to performing the hypodermic procedure).

It is another object of this invention to provide a safety hypodermic apparatus which conforms to existing procedures for aspirating medication into a syringe, administering injections, and allowing unrestricted access for vascular access or catheter insertion.

It is yet another object of this invention to provide a safety hypodermic apparatus which provides an exposed sharpened tip for bevel-up needle viewing.

It is still another object of this invention to provide a safety hypodermic apparatus which automatically and /or manually entraps or captures the sharpened tip of the needle after use.

It is a further object of this invention to provide a safety hypodermic apparatus which allows medication or diluent to be aspirated into a syringe without prematurely activating the automatic and/or manually covering safety mechanism.

It is a still further object of the invention to provide a safety hypodermic apparatus which can be used with a double lancet needle for piercing a cartridge in a pre-filled syringe, or a stopper in a blood collection vacuum tube.

It is an additional object of this invention to provide a safety hypodermic apparatus which lends itself to automated manufacturing.

It is another object of this invention to minimize any mechanical resistance or component fatigue inherent to the stored energy components of the invention when the hypodermic needle is stored.

It is yet another object of the invention to leave the delicate, sharpened needle tip untouched during assembly procedures, ensuring the sharpest needle tip possible to minimize any patient discomfort during use of the hypodermic device.

It is a further object of the invention to reduce the number of components to the lowest possible number needed to accomplish the intended task of providing acceptable, low cost, fail-safe, single-use hypodermic devices for the healthcare industry.

It is yet another object of the invention to prevent catheter separation from the catheter carrying device until the needle tip is safely contained in a protective cover.

In one embodiment the needle guard assembly of the present invention includes a needle guard that is slidably mounted on a hypodermic needle having a needle tip located at the distal end of the needle. The needle guard contains a movable needle trap that is biased against or toward the hypodermic needle. The needle trap

advances over the tip of the needle, entrapping the needle tip as the needle guard is urged forward near the sharpened distal end of the hypodermic needle. A tether, or other limiting means, limits the forward movement of the needle guard along the needle. In one embodiment, the needle guard is manually urged forward along the shaft of the needle by the user. In yet another embodiment, a spring, or other biasing means, is used to move the needle guard along the shaft of the needle.

In another embodiment, a hypodermic needle is attached to a housing or hub. A coil spring is positioned between the hub, or housing, and the needle guard assembly. The spring provides the biasing force for advancing the needle guard assembly forward along the shaft of the needle. Prior to use, the needle guard assembly is releasably retained near the proximal end of the needle by a latching arm that is attached to the hub or housing. In one embodiment, the latching arm is automatically disengaged from the needle guard when a longitudinal compressive force is exerted on the retained needle guard. In yet another embodiment, the latching arm may be disengaged manually by the user.

In another embodiment, a side-loadable needle guard assembly is provided that permits the needle tip protective device to be assembled without disturbing the delicate sharpened needle tip. In one embodiment the side-loadable needle guard assembly includes a slotted configuration. In yet another embodiment, the side-loadable needle guard assembly includes a "clam-shell" configuration.

In yet another embodiment, the needle guard assembly includes a coupling mechanism that prevents a mechanical

separation from the catheter until the needle tip is safely contained within the needle trap. In one embodiment, the coupling mechanism includes an arm having a proximal end and a distal end. The proximal end of the arm is attached to the movable needle trap. The distal end of the arm includes a projection that is releasably retained within a recess of a catheter hub. Hence, as the needle trap moves inward to entrap the needle tip, the arm also moves inward. The inward movement of the arm causes the arm's distal projection to be released from the catheter hub recess, thereby permitting a separation between the needle guard assembly and the catheter hub.

Other objects and benefits of this invention will become apparent from the description which follows hereinafter when read in conjunction with the figures that accompany it.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a full side view of a prior art hypodermic needle attached to a hub.

Figure 2 is a front view of the hypodermic needle hub shown in Figure 1.

Figure 3A is a full side view of the hypodermic needle hub shown in Figure 1.

Figure 3B is a full top view of the hypodermic needle hub shown in Figure 1.

Figure 4 is a cross sectional view of the hypodermic needle hub shown in Figure 1.

Figure 5 is a full side view of a hub in accordance with one embodiment of the present invention.

Figure 6 is a cross sectional view of the hub shown in Figure 5.

Figure 7 is a cross sectional view of the hub shown in Figure 5 having a flange section for retaining a removable cover.

Figure 8 is a full side view of the hub shown in Figure 7 with the addition of a protrusion for engaging a removable cover.

Figure 9 is a full rear view of the needle hub shown in Figure 7.

Figure 10 is a full front view of the hub shown in Figure 7.

Figure 11 is a full front view of a needle guard assembly in one embodiment of the present invention.

Figure 12 is a full front view of the needle guard assembly shown in Figure 11.

Figure 13 is a full outside view of a needle guard assembly and tether in one embodiment of the present invention.

Figure 14 is a full side view of one embodiment of the present invention comprising a unitary construction.

Figure 15 illustrates one embodiment of the present invention in a ready-to-use state.

Figures 16-18 illustrate the needle guard assembly being activated to cover the tip of a hypodermic needle.

Figures 19-22 illustrate other embodiments of the present invention.

Figure 23 illustrates another embodiment of the present invention.

Figures 24 and 25 show the present invention attached to a blood collection device.

Figure 26 shows the present invention included in a catheter device.

Figure 27 shows the present invention unitarily attached to a syringe.

Figures 28 and 29 show a needle guard in accordance with one embodiment of the present invention.

Figures 30 shows a needle trap that is biased against or towards the hypodermic needle.

Figures 31 shows a needle entrapped within a needle guard assembly in one embodiment of the present invention.

Figure 32 illustrates a tether in one embodiment of the present invention.

Figure 33 illustrates a needle trap in one embodiment of the present invention.

Figure 34 is a full open view of a needle guard assembly in one embodiment of the present invention

Figure 35 is a exploded view of one embodiment of the present invention.

Figure 36 is an isometric open view of the needle guard shown in Figure 34.

Figure 37A shows the needle tip guard assembly of Figure 35 in a ready to use state.

Figure 37B shows the needle tip guard assembly of Figure 37A after it has been activated.

Figures 38A and 38B show a needle tip protective device attached to a fillable syringe in a ready-to-use and shielded position, respectively.

Figure 39A and 39B show a needle tip protective device attached to a prefilled syringe in a ready-to-use and shielded position, respectively.

Figures 40A and 40B show a needle protective device attached to a prefilled cartridge.

Figure 41A and 41B show a needle protective device attached to a blood collection apparatus in a ready to use and shielded position, respectively.

Figure 42A and 42B illustrate another embodiment of the present invention.

Figure 42C illustrates a needle guard assembly in one embodiment of the present invention.

Figures 43A and 43B show separate embodiments of the needle guard assembly of the present invention.

Figure 44A illustrates another embodiment of the present invention.

Figure 44B illustrates an enlarged cross-section view of the needle guard shown in Figure 44A.

Figures 45A-C, 46 and 47 illustrate a needle hub in one embodiment of the present invention.

Figure 48A-C illustrate several retrofit hub configurations in accordance with the present invention.

Figure 49A shows a full side view of the present invention attached to a prior art needle hub.

Figure 49B is a cross-sectional view of Figure 49A.

Figure 50 is cross-sectional side view of the present invention attached to a prefilled syringe.

Figure 51 is cross-sectional side view of the present invention attached to a prefilled cartridge syringe hub.

Figure 52 is a cross-sectional side view of the present inventions intergrally molded to a prefilled cartridge syringe hub.

Figure 53 is cross sectional side view of a prior art I.V. catheter adapter.

Figure 54 shows the present invention retrofitted to an I.V. catheter adapter.

Figure 55 shows the present invention integrally molded to an I.V. catheter adapter.

Figure 56 illustrates the present invention attachable to a blood collection device.

Figure 57 illustrates a full front view of a needle guard assembly in one embodiment of the present invention.

Figure 58 is a cross sectional side view of a prior art prefilled syringe cartridge hub.

Figure 59 is a cross sectional side view of the present invention being threadedly attached to a glass cartridge hub.

Figure 60 is a cross sectional side view of the present invention fixedly attached to a glass cartridge.

Figures 61-63 illustrate a catheter in accordance with one embodiment of the present invention.

Figure 64-67 illustrate another embodiment of the present invention.

Figure 68 illustrates a full side view of another embodiment of the present invention.

Figures 69-77 illustrate a needle guard assembly in accordance with one embodiment of the present invention.

Figures 78 is a cross sectional side view of the present invention for use on a male luer syringe in a ready-to-use state.

Figure 79 is a cross sectional side view of the present invention for use on a prefilled syringe or a prefilled cartridge syringe in a ready-for-use state.

Figure 80 is cross sectional side view of the hub and cover shown in Figure 78.

Figure 81 is a cross sectional view of the needle and cover shown in Figure 79.

Figure 82 and 83 illustrate a collar for use in one embodiment of the present invention.

Figure 84 illustrates another embodiment of the present invention.

Figure 85 illustrates yet another embodiment of the present invention.

Figure 86 is a graph depicting the interaction of a resilient member and a sliding member without a needle guard notch.

Figure 87 is graph depicting the interaction of resilient member and a sliding member with a needle guard notch.

Figures 88-94 illustrate a number of different embodiments of the present invention.

Figure 95 and 96 illustrates a full side view of a needle hub in one embodiment of the present invention.

Figures 97-102 show the embodiments of Figures 50, 51, 52, 54 and 55 with a needle having a change in contour.

Figures 103-105 illustrate a catheter in yet another embodiment of the present invention.

Figures 106-108 show a cross sectional view of another embodiment of the present invention.

Figures 109-113 illustrate a side-loadable needle guard in one embodiment of the present invention.

Figures 114 and 115 show a needle guard assembly for use in a catheter.

Figures 116 and 119 show a needle trap in one embodiment of the present invention.

Figure 117 is a full top view of a housing in one embodiment of the present invention.

Figure 118 illustrates a cross sectional and cut-away view of a catheter introducer in one embodiment of the present invention.

Figures 120 and 121 illustrate catheter assemblies in yet other embodiments of the present invention.

Figures 122A-122C show an isometric view of a catheter in one embodiment of the present invention.

Figures 123 and 124 show a needle trap assembly for use in a catheter.

Figures 124 -130 illustrate a needle guard in yet another embodiment of the present invention.

DETAILED DESCRIPTION

A needle tip protective device is described. In the following description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be obvious to one of ordinary skill in the art that the invention may be practiced without these specific details. In other instances, well-known structures and processing steps have not been shown in particular detail in order to avoid unnecessarily obscuring the present invention. Additionally, it should be noted that throughout this discussion reference will be made to a variety of hypodermic needle devices such as fillable syringes, prefilled syringes, prefilled cartridge syringes, blood collection devices and catheters. It is appreciated, however, that the present invention is not limited to these devices, and may be used in any application where it is desirable to provide a protective covering at the tip of a needle or other elongated object.

Also keep in mind that the needle covering invention disclosed herein in regard to an I.V. catheter can easily be adapted to all types of other catheters where a needle may be used, including, but not limited to, neurological, urological, central venous, oximetry, thermodilution, PTCA, PTA, angiography, atherectomy, enlectrophysiology, suction and wound drainage, cardiovascular, pulmonary and spinal catheters. The needle covering invention described herein on a syringe can also be easily adapted to a blood collection needle, or any other needles used in invasive procedures, including, but not limited to, angiography, cardiovascular,

ophthalmological, orthopedic, dentistry, veterinary, chemotherapy and arterial blood gas.

Figure 1 is a full side view drawing of a prior art standard, exposed hypodermic needle 10, having a sharpened needle tip 11 at the distal end with the opposite, or proximal end of the needle 10 attached to a hub 12, with at least one flange 1 at the very proximal end for attaching the needle hub 12 to a male luer fitting, a needle nest 4 at the distal end of the needle hub 12, for fixedly attaching the needle 10, and a plurality of fins 2 on the needle nest 4.

Figure 2 is a full front view drawing of the prior art hypodermic needle hub 12 with an aperture creating a fluid/gaseous path to the hypodermic needle, a needle nest 4 for fixedly attaching the hypodermic needle 10 therein, with the needle nest 4 surrounded by a plurality of fins 2 and a plurality of flanges 1.

Figure 3A is a full side view drawing of the prior art hypodermic needle hub 12 with at least one flange 1 for attaching the needle hub 12 to a male luer fitting, a needle nest 4 for fixedly attaching the needle (not shown here) and a plurality of fins 2.

Figure 3B is a full top view drawing of the prior art hypodermic needle hub 12 with at least one flange 1 for attaching the needle hub 12 to a male luer fitting, a needle nest 4 for fixedly attaching the needle (not shown here) and a plurality of fins 2.

Figure 4 is a cross-sectional view of the prior art hypodermic needle hub shown in Figure 2 along axis 4-4 comprising a hub portion 12 with a flange 1, an aperture creating a fluid/gaseous path to the hypodermic needle (not shown here), a needle nest 4 for

fixedly attaching a hypodermic needle (not shown here), and a plurality of fins 2.

Figure 5 is a full side view drawing of the hub section of the disclosed invention comprising a hypodermic needle hub 112 with at least one flange 101 for attaching the needle hub 112 to a male luer fitting, a needle nest 104 (not shown here) for fixedly attaching the needle (not shown in this view), an inner aperture creating a fluid/gaseous path between the needle hub 112 and the needle (not shown here), a protrusion 5 located at the distal end of the needle hub 112, the protrusion being connected to the extended sidewall section 15 at the distal end of the needle hub 112, and a moveable latching arm 26 with a finger pad 27 attached to the needle hub 112 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the needle hub 112, said moveable latching arm 26 shown in the preferred molded position.

Figure 6 is a cross-sectional side view of Fig. 5. Needle hub 112 includes an inner aperture that provides a fluid/gaseous path between the needle hub 112 and the needle (not shown here). Arrow "M" indicates the directional movement of latch 26.

Figure 7 is a cross-sectional side view of Fig. 5 having a section 16 for removably holding a removable cover over the hypodermic needle.

Figure 8 is a full side view of the hub 112 shown in Fig. 7, with the addition of at least one protrusion 14 located adjacent to section 16, said protrusion 14 being engagable with a removable cover. Protrusion 14, in conjunction with a contacting member of removable

cover, is positioned to facilitate attachment or removal of a hypodermic needle from a connecting device. Hub 112 also includes a protrusion or cleat 17 with a cap or holding means 18 to attach a tether.

Figure 9 is a full rear view of needle hub 112 shown in Figure 7.

Figure 10 is a full front view drawing of the disclosed hub invention comprising a hypodermic needle hub 112 with an extended wall section 15, an aperture creating a fluid/gaseous path to the hypodermic needle (not shown), a needle nest 104 for fixedly attaching the needle (not shown), a protrusion 5 which can be used as a guide for aligning another component, a section 16 for removably holding a removable cover over the hypodermic needle (not shown here), a protrusion 14 located adjacent to section 16 for engaging a corresponding component of a removable cover (not shown), and a moveable latching arm 26 with a finger pad 27 attached to the needle hub 112 by a hinge section 23 (not shown).

Figure 11 is a full front view of a needle guard assembly 22 positioned on the front of the hub 112 comprising a guide aperture 47 with a hypodermic needle 10 therethrough, said aperture 47 being created by coupling the open-faced sections of the needle guard assembly 22 together at a split line 43, a protrusion 5 which is used as a guide for aligning the needle guard assembly 22 on the hub 112 whereby an aperture is created on the needle guard assembly 22 when the open-faced sections of the needle guard assembly 22 are coupled together, a section 16 for removably holding a removable cover over the hypodermic needle 10, a protrusion 14

located adjacent to section 16 for engaging a corresponding component of a removable cover (not shown). In one embodiment needle guard 22 also includes a moveable latching arm that is attached to needle hub 112 by a hinge section. A tether (not shown) is generally used to fixedly attach needle guard 22 to hub 112.

Figure 12 is a full front view of the needle guard assembly 22 shown in Figure 11 comprising a guide aperture 47 created by coupling the open-faced sections of the needle guard assembly 22 together at the split line, 43, a recess 25 with a protrusion 44 at the rear or inner end of the recess 25, a tether 24 connected to a hinge section 28 and an aperture adjacent to the hinge section.

Figure 13 is a full outside, top view of the needle guard assembly 22 and tether 24 as manufactured comprising an open-faced needle guard 22 with a hinge section 28, with adjacent lands 39 which create an aperture when the needle guard assembly 22 is coupled together, a needle tip guard 41 with a hinge section 40 allowing the needle tip guard 41 to move, a recess 25 with a protrusion 44 and a tether 24 with a connector or loop 20.

Figure 14 is a full side view of a unitary, one piece embodiment of the invention comprising a hypodermic needle hub 112, having at least one flange 101, an extended wall section 15, a protrusion 5, a moveable latching arm 26 connected to said hub 112 by a hinge 23, said latching arm having a finger pad 27 at the proximal end and a hooking protrusion 21 at the distal end, a protrusion 17 connecting a tether 24 to a slidable needle guard assembly 22, with a moveable needle tip guard 41 and a hinge section 40. In addition to serving as

an alignment guide needle guard 22, protrusion 5 may also serve as an aspiration stop when a needle is inserted into a medicine vial.

Figure 15 is a full side view of the invention shown in the ready to use configuration comprising a hypodermic needle 10 with a sharpened tip 11, a needle hub 112, with at least one flange 101, an extended sidewall section 15, a section 16 for removably attaching a cover, a protrusion 14 located adjacent to section 16, said protrusion 14 being engagable with a removable cover, said protrusion 14 in conjunction with corresponding member of removable cover, being positioned to facilitate attachment or removal of a hypodermic needle from a connecting device, a moveable latching arm 26 connected to hub 112 by a hinge 23, said latching arm having a finger pad 27 at the proximal end and a hooking protrusion 21 at the distal end, said latching arm 26 releasably holding said needle guard 22 and a compressed resilient member 19 in a retained position, said needle guard 22 having a moveable needle tip guard 41 which is biasly contacting the hypodermic needle, a protrusion 5 on the hub 112 for aligning a needle guard assembly 22 to the needle hub 112 so the moveable latching arm 26 properly enters the corresponding recess 25 on the needle guard assembly 22, said needle guard assembly 22 being connected to said hub 112 by a tether 24.

Figure 16 is a full side view Figure 15 with a compressive longitudinal force being exerted on the needle guard assembly 22, whereby the needle guard assembly 22 and compressed resilient member 19 move enough to release the hold by the protrusion 21 of the moveable latching arm 26.

Figure 17 is a full side view Figure 15 with the released needle guard assembly 22 being urged to the distal end of the hypodermic needle 10 by the extending force of the resilient member 19, said needle tip guard 41 is biasly contacting said hypodermic needle 10 by the inherent memory of the molded configuration of said needle tip guard 41 and/or the extending force of the surrounding resilient member 19.

Figure 18 is a full side view Figure 15 with the resilient member 19 extended and still exerting force on the needle guard assembly 22, said resilient member 19 assists inherently molded bias of needle tip guard 41 by urging said needle tip guard 41 inwardly and ahead of the sharpened needle tip, said needle guard assembly 22 is limited from advancing further by the extended tether 24, with the sharpened hypodermic needle tip being entrapped within the needle guard assembly 22, with the needle tip guard 41 now securely positioned ahead of the sharpened needle tip said needle tip guard 41 blocking the aperture guide of the needle guard assembly 22, ensuring safe containment of the sharpened tip.

Figure 19 is a full bottom view of Figure 15 showing the elements of the invention and a rectangular finger pad configuration, although the finger pad configuration only needs to be suitable (round, square, triangular or the like) to facilitate a manual force to release the hold on retained needle guard assembly 22, said needle guard assembly 22 having a recess 25 for engaging the distal end of the movable latching arm 26 to the corresponding section on the needle guard assembly 22.

Figure 20 is a full top view of Figure 15 showing the elements of the invention and having a tether 24 which can have a round, square, elliptical or ribbon-like cross section and hinge section 28. It is important to note that the tether can comprise either rigid or flexible characteristics, and can be unitary molded with other components, or be a separate component. A rigid tether would have to be able to slide along the side of a syringe, prefilled syringe or cartridge, blood collection needle holder or I.V. catheter when the device is used, and said tether could slide through an aperture which would limit the axial forward movement of the tether and needle guard. This rigid tether would have to have a proximal end larger than the aperture, so the tether would be limited in its slidable movement.

A flexible tether can be made more resilient or rigid by changing the molecular alignment of the molecules of the tether component by stretching, heating, radiation processing or the like. The tether can be manufactured separately, or connected to either the hub component, the needle guard assembly or the needle guard housing. The tether could be comprised from a single variety, or a combination of materials including, but not limited to: plastic resin, synthetic material, organic material, cloth, woven material, stranded material, metal, silk, or a composite material.

Figure 21 is a full side view of Figure 15 having an extended protrusion 105 for preventing premature release of the releasable needle guard assembly 22. This embodiment can be used for blood collection purposes, indwelling catheter placement or preventing premature activation during medicine aspiration.

Figure 22 is a full top view of Figure 15 having an extended protrusion 105 for preventing premature release of the releasable needle guard assembly 22.

Figure 23 is a cross-sectional view of the invention ready for use having the elements described herein, with the resilient member 19 in a compressed position with the needle guard assembly releasably held by the protrusion 21 of the moveable latching arm 26, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 112, and an aperture 47 with a hypodermic needle 10 therethrough, said latching arm 26 having a protrusion 49 for engaging said needle guard assembly 22 when said needle guard assembly is moved toward said hub portion 112, said protrusion 49 manually moves said latching arm 26 in an outward manner ensuring said latching arm 26 moves outwardly releasing the hold on the needle guard assembly 22.

Figure 24 is a full side view of the invention for blood collecting purposes showing the elements described and notated in the previous drawings in addition to a double-lancet hypodermic needle 110 having a sharpened tip 11 at the distal end and a sharpened tip 111 at the proximal end (see Figure 25), a hub 212 having a threaded section for removably attaching the hub into a needle holder 45 (see Figure 25) by means of threads 74, and a piercable, collapsible cover 48 on the distal end of the needle 110 and a protrusion 105.

Figure 25 is a full side view of the invention for blood collecting purposes showing the elements described and notated in the previous drawings in addition to the invention being removably

attached to a needle holder 45, said needle holder 45 having a larger opening at the proximal end for inserting a removable blood collection tube, and a smaller opening at the distal end for removably attaching a blood collection needle 110 and hub 212. A manual releasing means is activated by pressing the finger pad 27 in a downward or inward manner, this is indicated by the arrow "F" pointing toward the finger pad 27.

It may be noted that the attachment means of connecting the invention to a blood collection needle holder 45 is not limited to the threaded means 74 shown throughout this application. Other attachment means, such as frictional engagement, snap fit, wedging or the like may also be used to accomplish the same function.

Figure 26 is a full side view of the invention with a removable, indwelling catheter, having a hub 312 attached to a hollow bore needle 210 with a distal stylet 211 and a removable, indwelling catheter 51 and catheter hub 50 slidably disposed on said needle 210. All other elements notated are described in the previous drawings.

Figure 27 is a full side view of the invention in a ready to use state unitarily attached to a syringe 6 by the hub 112. All other elements notated are described in the previous drawings.

Figure 28 is a full front view of the needle guard assembly shown in an open-faced configuration comprising a needle guard assembly 22 having a hinge section 28 joining each section, a split line 43 where the sections mate together, an aperture guide 47 on each section, a recess 25 on one section having a protrusion 44 for joining with the corresponding element 144 on the other section of

said needle guard assembly 22, a moveable needle tip guard 41 and a post 36 for joining the needle guard assembly 22 sections together.

Figure 29 is a full rear view of the needle guard assembly shown in an open-faced configuration comprising a needle guard assembly 22 having a hinge section 28 joining each section, a split line 43 where the sections mate together, an aperture guide 47 on each section, a protrusion 44 for joining with the corresponding element 144 on the other needle guard assembly 22 section, a moveable needle tip guard 41, at least one post or protrusion 36 on one needle guard assembly 22 section which enters at least one corresponding slot 37 on the other needle guard assembly 22 section for securing the sections together.

Figure 30 is a cross-sectional side view showing the interaction of the needle guard assembly 22 with the resilient member 19 and hypodermic needle 10 and sharpened needle tip 11, comprising a moveable needle guard assembly 22 with a hypodermic needle 10 therethrough, with resilient member 19 urging the needle guard assembly 22 toward the distal end of the hypodermic needle 10. The needle guard assembly 22 having a moveable needle tip guard 41 with a hinge section 40, said needle tip guard 41 is molded in a manner whereby the needle tip guard 41 comprises an inherent biasing force toward the hypodermic needle 10, another biasing force is exerted on the needle tip guard 41 by the extending force of the resilient member 19, said needle tip guard 41 enters the corresponding recess 31 when said needle tip guard 41 advances beyond the sharpened needle tip 11, said needle tip guard 41 slidably contacts said hypodermic needle 10. The needle guard 22 is

attached to a hub element 12 by means of a tether 24 as described and notated in the previous drawings.

Figure 31 is cross-sectional side view showing containment of the sharpened needle tip 11 within the needle guard assembly 22 comprising a needle guard assembly 22 with a hypodermic needle 10 therethrough, said needle guard assembly 22 being urged beyond the distal end of the hypodermic needle 10 and sharpened needle tip 11 by the extending force of a resilient member 19 whereby the moveable, self-biasing needle tip guard 41 of the needle guard assembly 22 moves in front of the sharpened needle tip 11, containing the sharpened needle tip 11 within the needle guard assembly 22 and behind the substantially impenetrable needle tip guard 41 having a hinge section 40. Additionally, the extending force of the resilient member 19 urges the needle tip guard 41 inwardly to a covering position, said resilient member 19 surrounds both the needle guard assembly 22 and the outer wall of the needle tip guard 41 holding the needle tip guard 41 in a closed, protective position by a radially confining force. In the protected, closed position, the needle tip guard 41 enters the corresponding recess 31 of the needle guard assembly 22, preventing movement and ensuring safe containment of the sharpened needle tip 11 within the needle guard assembly 22. The needle guard 22 is attached to a hub or housing by means of a tether as described and notated in the previous drawings.

Figure 32 is a full top view of a separate tether 24 with connecting loops 20 at the proximal and distal ends. This tether

embodiment is used with a separate hub component and separate needle guard assembly component.

Figure 33 is a cross sectional side view of the needle guard assembly 22 comprising a needle tip guard 41 having a hinge section 40 connected to the needle guard assembly 22. Said needle tip guard 41 is molded in a self-biasing manner as shown and is moveable to an open and closed position. Said needle tip guard may comprise a substantially impenetrable plastic resin and/or a substantially impenetrable metal.

Figure 34 is a full open view of the interior of the open-face needle guard assembly 22 as manufactured and before being joined together. Said needle guard assembly 22 comprising two joining sections which are connected by a hinge section 28 having a tether 24, one needle guard assembly section having a moveable, self-biasing, substantially impenetrable needle tip guard 41 with a moveable hinge 40 connected to said needle guard assembly 22, a post or protrusion 36, a recess 25 with a protrusion 44 and a recess 38 for nesting said needle guard assembly 22 adjacent to the needle hub 112, 212 or 312 as shown in the previous drawings; with the corresponding needle guard assembly section having a corresponding slot 31 for said needle tip guard 41 to enter, a slot 37 for receiving the corresponding post 36, a proximal inner guide section 35 and a distal inner guide section 47 for the hypodermic needle 10 (not shown), a corresponding receiving section 144 for recess 25 and protrusion 44, and a recess 38 for nesting said needle guard assembly 22 adjacent to the needle hub 112, 212 or 312 as shown in other drawings herein.

Figure 35 is a full, exploded view of the invention having the elements described herein the other accompanying drawings comprising a slidable needle guard assembly 22 in the closed face configuration having a tether 24 and loop 20; a resilient member 19; and a hypodermic needle 10 fixedly attached the needle hub. Figure 36 shows needle guard assembly 22 in a full view, open-faced configuration. The open face, or "clam-shell" configuration of the needle guard make this embodiment feasible using standard injection molding techniques. The sharpened needle 10 is first attached to the hub portion 112, then the needle 10 is coated with a friction-reducing lubricant, the resilient member 19 is concentrically disposed over the needle 10 and compressed, then the needle guard assembly 22 is assembled from the side of the needle 10 keeping the sharpened tip 11 from being contacted, the needle guard assembly 22 and tether 24 are then attached to the hub 122 by a connecting means 20.

The extended wall section 15 can be eliminated for the invention to work, but shields the resilient member 19. The elements of the needle guard assembly 22, in relation to each other, and in relation to the bevel of the sharpened needle tip 11, can also be oriented as may be deemed necessary to suit a specific procedure or purpose.

Figure 37A is an isometric drawing of a needle tip protective device 500 in one embodiment of the invention. Figure 37A shows protective device 500 in a ready-to use position. Figure 37B shows the protective device 500 shielding the needle tip within the needle guard assembly 22.

Figure 38A and 38B show a needle tip protective device 500 in one embodiment of the invention attached to a fillable syringe 501 in a ready-to-use position and a shielded position, respectively.

Figure 39A and 39B show a needle tip protective device 500 in one embodiment of the present invention attached to a prefilled syringe 502 in a ready-to-use position and a shielded position, respectively.

Figure 40A and 40B show a needle protective device 500 in one embodiment of the invention attached to a prefilled cartridge 503. Figure 40A shows the prefilled cartridge 503 before use. Figure 40B shows the prefilled cartridge 503 after the protective device 500 is activated.

Figure 41A and 41B shows a needle protective device 500 in one embodiment of the invention attached to a blood collection device 504 in a ready-to-use position and a shielded position, respectively.

Figure 42A illustrates a needle tip guard assembly in yet another embodiment of the present invention for protecting the distal tip 11 of a standard hypodermic needle 10. The assembly includes a needle guard 22 that is slidably mounted on needle 10. Needle guard 22 contains a movable needle trap 41 that is biased against or toward the shaft of needle 10. Needle trap 41 advances over the tip 11 of the needle 10, entrapping the needle tip 11, when needle guard 22 is positioned near the distal tip of needle 10. Figure 42B shows distal needle tip 11 captured within needle guard 22. In the embodiment of Figure 42A, needle guard 22 is moved forward along the shaft of needle 10 by the user. In Figure 42A, needle trap

41 is shown as a detachable element of needle guard 22 that is insertable into a slot 80 located adjacent the proximal end of needle guard 22. Needle trap 41 generally comprises a flexible metal member. Other impregnable materials that are not susceptible to fatigue may also be used. For example, some plastics or other resin based materials may be used. In such instances, needle trap 41 may be integrally molded with needle guard 22. A recess 31 may be included within needle guard 22 for receiving needle trap 41. A flexible tether 24 limits the forward movement of the needle guard 22 along the needle 10. Other limiting means, such as, for example, a change in contour in needle 10 or the use of a rigid tether assembly may be used in lieu of the flexible tether. These limiting devices will be described in greater detail later in this description.

Figure 42C shows needle guard 22a that is another embodiment of the needle guard 22 shown in Figures 42A and 42B. The needle guard 22a of Figure 42C includes an integrally molded needle trap 41a, a notch 61a, a recess 61b in trap 41a, and needle guard 22, respectively. A resilient member 102 is held within notch 61a and recess 61b. The stored energy of resilient member 102 urges needle trap 41a toward or against needle 10. Resilient member 102 may comprise a "v" shape or may simply comprise a member that has been curved to create a stored energy.

Figure 43A is a full side view one embodiment of the present invention with the resilient member 119 extended and still exerting force on the needle guard assembly 22, said resilient member 119 assists inherently molded bias of needle guard trap 41 by urging said needle guard trap 41 inwardly and in front of the sharpened

needle tip 11 (see Figure 33), said needle guard assembly 22 is limited from advancing further by the limiting tether 24, with the sharpened hypodermic needle tip being entrapped within the needle guard assembly 22, with the needle guard trap 41 now securely positioned in front of the sharpened needle tip 11 said needle guard trap 41 blocking the aperture guide opening 47 of the needle guard assembly 22, ensuring safe containment of said sharpened tip 11 within the needle guard assembly 22. The needle guard trap 41 is attached to the needle guard assembly 22 by a hinge section 40. A hollow bore hypodermic needle 10 is fixedly attached to a hub 112, said hub 112 having at least one proximal flange 101 for attaching said hub 112 to a male luer fitting, said hub 112 also having a flange 16 for removably attaching a protective storage cover (not shown), said flange 16 having at least one shoulder or projection 14 for interfacing with a corresponding portion of a storage cover to allow twisted attachment and/or removal of said hub 112 to or from a medical device, said hub also having a body portion 15, a protrusion 5, and a movable latching arm 26, said latching arm 26 being fixedly attached to said hub body 15 by a hinge section 23, said latching arm also having a hook 21, a protrusion, cam, or ramp 49 and a finger pad or button 27.

Figure 43B shows the protective needle guard assembly of Figure 43A attached to a syringe 6. The protective needle guard assembly may be integral to syringe 6, or may be attached as an add-on component.

Figure 44A is a full side view of the disclosed invention with the resilient member 119 extended and still exerting an extending

force on the needle guard assembly 22, said resilient member 119 assists inherently molded bias of needle guard trap 41 by urging said needle guard trap 41 inwardly and in front of the sharpened needle tip 11 said needle guard assembly 22 is limited from advancing further by the limiting tether 24, with the sharpened hypodermic needle tip 11 being trapped within the needle guard assembly 22, with the needle guard trap 41 now securely positioned in front of the sharpened needle tip 11. Said needle guard 22 having an extended slot section 44a for releasably holding said needle guard assembly 22 in a retained position. Said extended slot section 44a places the interface between the latching arm hook 21 and the needle guard assembly 22 away from any potential binding which may occur during needle insertion. If the retaining means interface is too close to the insertion surface, the latching arm 26 may be prevented from releasably holding the needle guard assembly 22. A flexible projection 107 is included within the needle guard assembly for retaining the end coil of spring 119 in a locked position after the needle tip protection device has been activated. Figure 44B illustrates a cross-sectional view of flexible projection 107. The needle guard trap 41 is attached to the needle guard assembly 22 at a hinge section 40. The needle 10 is fixedly attached to a hub 112, said hub 112 having at least one proximal flange 101 for attaching said hub 112 to a male luer fitting, said hub also having a body portion 15, a protrusion 5, and a movable latching arm 26, said latching arm 26 being fixedly attached to said hub body 15 by a hinge section 23, said latching arm also having a hook 21 and protrusion 49.

Figure 45A is a full side view drawing of the needle hub 412, in accordance with one embodiment of the invention comprising a hypodermic needle hub 412 with a flange 401 for attaching the needle hub 412 to a male luer fitting, a needle nest 404 for fixedly attaching the needle, a plurality of fins 402, and a land 75 for attaching another component to the hub 412.

Figure 45B is a full top view of the needle hub 412 shown in Figure 45B having a flange 401 for attaching the needle hub 412 to a male luer fitting, a needle nest 404 for fixedly attaching a needle, a plurality of fins 402, and a land 75 for attaching another component to the hub 412.

Figure 45C is a cross sectional side view of Figure 45A comprising a hypodermic needle hub 412 with a flange 401 for attaching the needle hub 412 to a male luer fitting a needle nest 404 for fixedly attaching the needle 10, an aperture therethrough creating a fluid/gaseous path from the said hub 412 to said needle 10, a plurality of fins 402, and a land 75 for attaching another component to the hub 412.

Figure 46 is a full side view drawing of the disclosed invention comprising a hypodermic needle hub 412 with a flange 401 for attaching the needle hub 412 to a male luer fitting, a needle nest 404 for fixedly attaching the needle, at least one, or a plurality of shortened fins 403, and a land 75 for attaching another component to the hub 412.

Figure 47 is a full front view drawing of Figures 45A and 46 comprising a hypodermic needle hub 412 with an aperture creating a fluid/gaseous path to the hypodermic needle 10, a needle nest 404

having adjacent at least one, or a plurality of fins 402 or 403, at least one, or a plurality of flanges 401 and a land 75.

Figure 48A is a is a full side view of the invention having a retrofitted hub portion 215 being fixedly attached to a hub portion 412 by a heatstake connection. Said hub portion 215 having an annular flange 16 for connecting a protective storage cover, a protrusion 17 for attaching a tether, said protrusion 17 having an aperture for insertably attaching or bonding the tether, said protrusion 17 having an angled proximal end to eliminate any possibility of the tether catching on the protrusion 17 when the needle guard 22 is activated. A hub portion 215 also includes a well or pocket 18 for removably inserting a tether in an out of the way fashion, and a retaining means 77 for releasably holding said needle guard 22 in a retained position adjacent to said hub portion 215.

Figure 48B is a full front view of the hub 215 described in Figure 48A comprising a hypodermic needle hub 215 having an aperture with a plurality of slots which correspondingly fits onto the distal end of a hypodermic needle hub shown throughout this application, said slots accept the fin or fins 402 from said hub 412, an annular flange 16, a protrusion 17 for attaching a tether or the like, a well or pocket 18 for removably inserting a tether or the like, and a retaining means 77 having an aperture 78 for releasably holding said needle guard 22 in a retained position adjacent to said hub portion 215.

Figure 48C is a full front view of Figure 48A comprising a hypodermic needle hub portion 215, an aperture which correspondingly fits onto the distal end of a hypodermic needle hub

shown throughout this application, an annular flange 16. There is one slot shown with the aperture, and at least one slot is needed to secure the needle hub 412 and hub portion 215 together to keep the hub portion 215 and needle hub 412 aligned when a circumferential force is exerted on the adjacent components.

Figure 49A is a full side view of the disclosed invention being fixedly attached to a prior art needle hub 12 having at least one flange 1 for attaching the needle hub 12 to a male luer fitting, a section 16 for removably holding a protective storage cover 54 over the hypodermic needle 10 (shown in other drawings in this application), a protrusion 5 located at the distal end of the hub portion 15, said protrusion 5 being connected to the hub portion 15 at the distal end of the hub portion 15, said section 16 having a shoulder 14 for twistedly attaching said invention to said storage cover, and a moveable latching arm 26 with a finger pad 27, attached to the hub portion 15 by a hinge section 23, said finger pad 27 having at least one protrusion for creating a more positive grip or contact with said finger pad 27. Finger pad 27 also comprising a different, or bright color, which serves as a visual indicator for the user to easily locate the finger pad for manual release of said needle guard assembly 22 or the like, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position adjacent to said hub portion 15, said moveable latching arm 26 shown in the preferred molded position.

Figure 49B is a cross-sectional side view of Figure 49A showing the disclosed invention attached to a prior art needle hub 12 said needle hub 12 comprising a hypodermic at least one flange 1 for

attaching the needle hub 12 to a male luer fitting, on one side a needle nest 4 for fixedly attaching the needle (not shown) said needle nest 4 having at least one, or a plurality of fins 2 and an inner aperture creating a fluid/gaseous path between the needle hub 12 and the needle. The invention is shown being retrofitted to said prior art hub 12, said attachment means comprising a spin weld, sonic weld, heat weld, or mechanical attachment means as shown by the protrusion 64 being attached by means of a snap fit or friction fit, said needle nest 4 having a recess or slot manufactured to accept said protrusion 64 of hub portion 15, said hub portion 15 having a protrusion 5 located at the distal end of the hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub portion 15 also having a section 16 for removably attaching a protective storage covers (not shown) said section 16 also having a means for creating a tortuous path preventing contamination from entering the sterile field created by enclosing the needle 10, needle guard 22 and hub portion 15 within a protective storage cover. Hub portion 15 includes a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having finger pad or button 27, a protrusion 21 for retaining a component in a releasably held position adjacent to the hub portion 15, said latching arm 26 also having a protrusion 49 for biasing the latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22 with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hypodermic needle hub 12.

Figure 50 is a cross-sectional side view of the invention attached to a prior art glass pre-filled syringe 6 having a nest bead 7 and a hypodermic needle 10 showing the disclosed invention attached to said glass pre-filled syringe 6. Hub body 15 is fixedly attached to syringe 6 at the nest bead 7 by the attaching section 65; said hub body 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub portion 15 having a fixedly attached tether 24, said hub body 15 also having a section 16 for removably attaching a protective storage cover a moveable latching arm or lever 26 attached to the hub body 15 by a hinge section 23, said lever 26 having a touch pad 27, a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub portion 15.

Figure 51 is a cross-sectional side view of the invention attached to a prior art pre-filled cartridge syringe hub 8a having a fixedly attached needle 10 with a sharpened proximal end 111 and a sharpened distal end, said sharpened proximal end 111 for piercing the stopper of a medicine or fluid cartridge. Hub portion 15 is fixedly attached to said syringe hub 8a at the needle nest 4 said hub portion 15 having a protrusion 5 located on said hub portion 15, said protrusion 5 having an attachment section 17 with an aperture for inserting a tether (not shown), said attachment section 17 having an

chamfered face on the proximal side to eliminate any possibility of the tether catching and hanging up on said attachment section 17 when said needle guard is released from a retained position, said hub portion 15 also having a section 16 for removably attaching a protective storage cover and a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably held position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging the latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub body 15.

Figure 52 is a cross-sectional side view of the invention integrally molded to a pre-filled cartridge syringe hub 8b having a fixedly attached needle 10 with a sharpened proximal end 111 and a sharpened distal end (not shown) said sharpened proximal end 111 is for piercing the stopper of a medicine or fluid cartridge. Integral hub portion 15 having a needle nest 4, protrusion 5 located on said hub portion 15, said protrusion 5 having an attachment section 17 with an slot for inserting a tether (not shown) said attachment section 17 having an chamfered face on the proximal side to eliminate any possibility of the tether 24 catching and hanging up on said attachment section 17, said hub portion 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge

section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position adjacent to the hub portion 15, said latching arm 26 also having a protrusion 49 for urging the latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard 22 (shown in other drawings in this application), with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub portion 15.

Figure 53 is a cross-sectional side view drawing of a prior art indwelling intravenous (I.V.) catheter 29 having a catheter mounting section 9 with a section 18 for removably attaching a protective storage cover, a fixedly attached hypodermic needle 10, and a male section 78 for removably attaching an indwelling I.V. catheter hub 13.

Figure 54 is a cross-sectional side view an I.V. catheter having a mounting section 9, a section 18 for removably attaching a protective storage cover a hypodermic needle 10 being fixedly attached to a needle nest 4; said catheter mounting section 9 being retrofitted with the present invention. The invention comprises a hub portion 15 being fixedly attached to said catheter mounting section 9 at the nest 4 by the attaching section 66, said hub portion 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected to the hub portion 15, said hub portion 15 having a fixedly attached tether 24, said hub portion 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26

having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging the latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard (not shown), with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub portion 15.

Figure 55 is a cross-sectional side view of the present invention integrally molded to an I.V. catheter mounting section 9.

Figure 56 illustrates a hub portion 15 of the present invention that may be attached to a blood collection device similar to that showing Figure 25.

Figure 57 is a full front view of the needle guard assembly 22 of Figure 11 further comprising at least one fin 63 protecting the movement of said latching arm 26, allowing said latching arm 26 to freely disengage when the needle guard 22 is moved towards the hub 12 when said needle guard 22 contacts the protrusion 49.

Figure 58. is a cross-sectional side view of a prior art pre-filled syringe cartridge comprising a glass cartridge 6, a glass cartridge hub 68 having a needle nest 4 for fixedly attaching a needle 10, said needle 10 having a sharpened distal end 11 said hub 68 also having a threaded section 67.

Figure 59 is a cross sectional side view of the invention being threadedly attached to a glass cartridge hub 68, said glass cartridge hub 68 being fixedly attached to a glass cartridge 6, said hub 68 having a needle nest 4 for fixedly attaching a needle 10, said needle 10 having a sharpened distal end (not shown) said hub 68 also

having a threaded section 67. Hub body 15 is fixedly attached to said glass cartridge hub 68 by the threaded section 67, said hub 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub portion 15 having a fixedly attached tether 24. Hub body 15 also includes a section 16 for removably attaching a protective storage cover (Figures 78 and 79), a moveable latching arm or lever 26 with a touch pad 27 attached to the hub body 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub body 15.

Figure 60 is a cross sectional side view of the invention being fixedly attached to a glass cartridge 6, comprising a hub 69 having a needle nest 4 for fixedly attaching a needle 10, a hub portion 15 being integrally molded to said hub 69; said hub portion 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub portion 15 having a fixedly attached tether 24, said tether 24 could also be fixedly attached to section 16, said hub 69 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26

having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard 22, with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on hub 69.

Figure 61 is a cross sectional top view of the invention shown on an indwelling catheter 29 embodiment, having a movable needle guard 22a and a separable indwelling I.V. catheter 29, said catheter 29 being fixedly attached to a catheter hub 13, an I.V. catheter mounting section 9 having a fixedly attached hollow bore hypodermic needle 10 having a sharpened distal end 11; a hub portion 15 having a section 16 for removably attaching a protective storage cover 54, a slidable needle guard 22a being fixedly attached to said hub portion 15 by means of a limiting tether, said needle guard 22a having a projection or finger post 80 for advancing said separable catheter 29 and said needle guard 22a along said hypodermic needle 10 so said catheter may be inserted into a blood vessel, said hypodermic needle 10 being slidable through a guide aperture 47 in said movable needle guard 22a, said needle guard 22a having a movable needle trap 41 with a corresponding slot 31 for receiving the needle trap 41 when said trap 41 moves beyond the needle tip 11, said needle guard 22a having an open collar or washer 30 for retaining the resilient member 19 on the proximal end of said needle guard 22a, said resilient member 19 being slidably held on said needle guard 22a by the notch or indentation 60, said movable

needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22a into notches 60 and/or 61, said needle trap 41 also having a notch or indentation 61 for retaining said end coils of said resilient member 19, with the distal end of said needle guard 22a having a male section 78 for removably attaching an indwelling I.V. catheter hub 13, with a section of said male section 78 having a movable arm 42 for releasably retaining a catheter hub 13 from said male section 78 during initial insertion of the catheter 29 into a patient. Said, catheter hub 13 having an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 42. Said movable arm 42 could also comprise a metal component which is inserted during or after said male section 78 is manufactured.

Said hub portion 15 could also comprise the latching arm 26 shown in other drawings in this application, otherwise said needle guard 22a would be releasably held adjacent to said hub portion 15 prior to use by a frictional or wedged means.

Figure 62 is a cross sectional top view of the movable needle guard 22a shown in Figure 61 on an indwelling catheter embodiment, containing the elements shown and described in the movable needle guard 22a, whereby the catheter 29 has been inserted in a blood vessel and the needle 10 is being retracted into said needle guard 22a as the needle 10 is being pulled away from said catheter insertion site, whereby the movable arm 42 on the male section 78 is free to move where the needle has been residing within the distal male section 78 of the needle guard 22a, allowing the catheter hub 13 to remain in the blood vessel and freely separate

from the needle guard 22a, with the needle trap 41 sliding on said needle 10. The needle guard 22a is attached to the hub portion 15 shown in Figure 61 whereby a fixedly attached tether (not shown) limits the forward movement of the needle guard 22a, safely trapping the needle tip 11.

Said catheter hub 13 having an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 42.

Figure 63 is a cross sectional top view of the movable needle guard 22a shown in Figures 61 and 62 on an indwelling catheter 29 embodiment, containing the elements shown and described in Figures 61 and 62, including the movable needle guard 22a, a tether (not shown) and catheter 29, whereby the catheter 29 has been inserted in a blood vessel and the needle 10 is safely retracted within said needle guard 22a where by the movable arm 42 has moved inwardly releasing the hold on the catheter hub 13, with the needle trap 41 now safely trapping the needle tip 11. Movable arm 42 includes a corresponding receiving slot 166 for receiving said movable arm 42. Said needle guard 22a having said movable needle trap 41 located within the corresponding slot 31 after said trap 41 has moved beyond the needle tip 11. Said needle guard 22a is attached to the hub portion 15 as shown in Figures 61 and 62 whereby a tether limits the forward movement of the needle guard 22a, safely trapping the needle tip 11. Said catheter hub 13 having an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 42.

The movable arm protrusion 42 can comprise a "v" shaped configuration which allows the catheter hub 13 to separate even in

the event the movable arm 42 has taken a set during storage. A set during storage could inhibit the separation of said catheter hub 13 from said mounting section 78.

Figure 64 is a cross-sectional side view of the present invention ready for use on a male luer syringe. Figure 64 shows a full view of the hypodermic needle 10 comprising: a hub 12 with a fixedly attached needle 10, a means for retaining a separate, movable needle guard 22, said needle guard 22 having an aperture therethrough for said hypodermic needle 10, whereby the needle guard 22 is retained in a ready to use position on said hub 12, with said retained needle guard 22 being urged away from said needle hub 12 by a compressed resilient member 19, said resilient member 19 being located between, among or amid said hub 12 and said needle guard 22, said resilient member 19 also being located in an annular fashion surrounding a portion of said needle guard 22, said needle guard 22 is fixedly attached to said needle hub portion 15 by means of a limiting tether 24.

Said hub 12 having an aperture therethrough creating a fluid/gas path to said hypodermic needle 10, at least one flange 101 for attaching the needle hub 12 to a male luer fitting, a needle nest 4 for fixedly attaching the needle 10, said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12 and an integral hub portion 15 having a protrusion 5 located at the distal end of said hub body 15, said protrusion 5 being connected to the hub portion 15, said protrusion 5 having a fixedly attached tether 24, said hub portion 15 also having a section 16 for removably attaching a protective storage

cover, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably retained position on the hub portion 15, said latching arm 26 also having a protrusion 49 for biasing the latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22; and a movable needle guard 22 having a proximal guide section 34, an internal guide section 35, with a recess or void 38 residing between said proximal guide section 34 and said internal guide section 35, a distal needle guide aperture 47, a receiving slot 31 to receive the needle trap 41 (not shown), a retaining area 44a with an aperture 48 to receive said protrusion 21, said needle guard 22 having a compressed resilient member 19 positioned at the proximal end of said needle guard 22 said with the resilient member 19 exerting an extending force on said needle guard 22; with said needle guard 22 being releasable held in a compressed position by the protrusion 21 of the moveable latching arm 26 on said hub portion 15, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 12, said aperture having the hub protrusion 5 positioned therethrough, said latching arm 26 having a protrusion 49 for engaging said needle guard assembly 22 when said needle guard 22 is urged toward said hub portion 12, said needle guard 22 engages protrusion 49 and manually moves said latching arm 26 in an outward manner ensuring said latching arm 26 moves outwardly releasing the hold on the needle guard assembly 22.

Figure 65 is a cross sectional top view of Figure 64 containing the elements shown and described in Figure 64 with the releasably held needle guard assembly 22 being releasably held adjacent to said hub portion 15, said guard assembly 22 being movable by the stored energy present in the compressed resilient member 19, said resilient member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19, said needle guard 22 having a proximal guide section 34, a distal needle guide aperture 47, a needle trap 41 biasly contacting said hypodermic needle 10 by the inherent memory of the molded configuration of said needle trap 41 and/or the extending force of the surrounding resilient member 19, whereby the advancing movement of said needle guard 22 is limited by a fixedly attached tether 24 (not shown), said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12. Said needle trap 41 being hingedly attached to said needle guard 22 by a hinge section 40, said needle guard 22 having a receiving slot 31 to receive the needle trap 41, a distal needle guide aperture 47.

Figure 66 is a cross sectional top view of Figures 64 and 65 containing the elements described in figures 64 and 65 with the releasably held needle guard assembly 22 being urged toward the distal end of the hypodermic needle 10 by the extending force of the resilient member 19, having a needle trap 41 biasly contacting said

hypodermic needle 10 by the inherent memory of the molded configuration of said needle tip guard 41 and/or the extending force of the surrounding resilient member 19, whereby the advancing movement of said needle guard 22 is limited by a fixedly attached tether (not shown). Said resilient member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19. Said needle trap 41 being hingedly attached to said needle guard 22 by a hinge section 40, said needle guard 22 having an integral metal guard 75 and a distal needle guide aperture 47. Said needle guard 41 also having a tapered or reducing proximal section 304 for non-binding access by the movable resilient member 19. Said resilient member 19 being movably positioned in an annular manner about or around the proximal section of said needle guard 22.

Figure 67 is a cross sectional top view Figures 64, 65 and 66 showing the needle tip 11 being trapped within the needle guard 22 by the movable needle guard 41, comprising a hypodermic needle 10 having a sharpened tip 11, said needle guard 22 being movably attached to said hub portion by means of a limiting tether (not shown), with the resilient member 19 extended and maintaining an extending force on the needle guard assembly 22, said needle guard is prevented from advancing further by the limiting feature of said limiting tether, said needle guard 22 having only one notch 60 for maintaining an extending force of said resilient member 19 on said

needle guard 22, said needle guard 22 maintaining alignment on said hypodermic needle 10 by means of the guide sections shown throughout this application. Said proximal guide 34 is shown here maintaining the needle guard 22 in a substantially concentric manner on said hypodermic needle 10. Said needle guard 41 also having a tapered or reducing proximal section 304 for non-binding access by the movable resilient member 19.

Figure 68 is a full side view of the invention without the needle 10, comprising a hub 12 that is attachable to a male luer fitting, said hub 12 having at least one flange 101 at the proximal end a hub portion 15, said hub portion 15 having a protrusion 5, a protrusion 17 having an aperture for attaching a tether 24, a movable latching arm 26 having a hook 21 and a protrusion 49, said latching arm 26 being hingedly attached to said hub portion 15 by a hinge 23, with said tether 24 being fixedly attached to a movable needle guard 22, said needle guard 22 having a movable needle trap 41 being hingedly attached to said needle guard 22 by the hinge 40, said needle trap 41 having at least one notch or multi-level landing 61 for proper positioning of a resilient member 19 (not shown), said needle trap 41 having a lead in section 33 also for locating said resilient member 19 in a compressed and/or extendible position, said needle guard 22 having a protrusion 44a for maintaining a releasable hold on said needle guard 22 when said needle guard 22 is retained adjacent to said hub portion 15 by said latching arm 26 and hook 21, said needle trap having a different, or brightly colored indicator 64 which is visible only when the resilient member is retained in a compressed positioned on said needle guard 22 before the needle

guard 22 is activated. The resilient member covers said indicator 64 shielding said indicator 64 from view when the needle guard 22 is activated and said resilient member 19 is extended around said needle guard 22 and the movable needle trap 41. Said resilient member 19 maintains said needle trap 41 in a protective position on said needle guard 22. Said indicator 64 could easily be located anywhere on said needle guard 22 where the advancing resilient member 19 hides the indicator 64 from view alerting the user that the device is safely shielding the sharpened needle tip 11 thus preventing an unintentional percutaneous needlestick injury.

Figure 69 is a full, outside, top view of the needle guard assembly 22 shown in its molded configuration comprising a foldable, open-faced needle guard 22 having a hinge section 28, with adjacent lands 39 which create an aperture when said needle guard assembly 22 is coupled together, a front section 62, at least one fin 63 for allowing adequate clearance for a latching arm to freely be urged from a releasably holding position on said needle guard 22 when the invention is activated during use. A slot or void 25 is created when the needle guard 22 sections are joined together. A retaining protrusion 44b is located adjacent to said slot 25, said retaining protrusion 44b interfaces with the hook of a latching arm (not shown), a notch 60 for positioning and maintaining the extending force of a resilient member on said needle guard 22 when said guard 22 is in a retained and extending mode, a tapered or reduced proximal end 45 for eliminating any binding effect caused when the resilient member moves around or about the proximal end of said needle guard 22, said needle guard 22 having a movable

needle trap 41 being hingedly attached to said needle guard by the hinge 40, said needle trap 41 having at least one notch or multi-level landing 61 for proper positioning of a resilient member said needle trap 41 having a lead in section 33 also for locating said resilient member in a compressed and/or extendible position. Said needle trap 22 being fixedly attached to a tether 24, said tether having at least one protrusion 20 for fixedly attaching said tether 24 to said hub portion 15 or hub 12, or flange 16.

Figure 70 is a view of the proximal end of the tether 24 having a plurality of protrusions 20a for fixedly attaching said tether 24 to said hub portion 15 or hub 12, or flange 16.

Figure 71 is a is a full, inside face view of the needle guard assembly 22 shown in its molded configuration comprising a foldable, open-faced needle guard 22 having a hinge section 28, with adjacent lands 39 which create an aperture when said needle guard assembly 22 is coupled together, a slot or void 25 is created when the needle guard 22 sections are joined together, a distal guide section 47 is also created when the needle guard 22 sections are joined together, a retaining protrusion ramp 44c is located adjacent to said slot 25, said retaining protrusion interfaces with the hook 21 of the latching arm 26 (both shown in other drawings in this application), said needle guard 22 having a movable needle trap 41 being hingedly attached to said needle guard by the hinge 40, said needle trap 41 having at least one skirt or fin 46 for entrapping said sharpened needle tip 11 (see Figure 75), said needle guard having a corresponding slot or opening 31 for receiving said needle trap 41, said needle guard 22 having at least one pin 36 and a corresponding

opening 37 for frictionally engaging said needle guard 22 sections together about a hypodermic needle, said pin 36 and slot 37 can be positioned on either side of needle guard 22 sections, said needle guard 22 having an internal guide section 35 and a proximal guide section 34 with a void or space 38 between said guides 34 and 35, said needle trap having an internal landing 52 located between said internal guide 35, with said landing 52 having an adjacent landing 53 which serves to guide the hypodermic needle during assembly, storage and use, said landing 53 also houses said sharpened needle tip within said needle guard 22. Said needle guard 22 being fixedly attached to a tether 24. Said tether 24 having at least one protrusion 20 for fixedly attaching said tether 24 to said hub portion 15 or hub 12, or flange 16.

Figure 72 is a full front view of the needle guard assembly 22 shown in an open-faced configuration comprising a needle guard assembly 22 having an internal guide section 35, a hinge section 28 with a plurality of needle guard 22 sections connected adjacent to said hinge section 28, said hinge section 28 having an adequate area for insert molding a separate tether or fixedly attaching a separate tether, said hinge section 28 also could have an aperture therethrough for fixedly inserting a separate tether, said needle guard 22 having a split line 43 where the needle guard 22 sections mate or join together, an aperture guide 47 on each section at the distal end, a recess 25 on one section having a protrusion 98a for joining with the corresponding element 98b on the other section of said needle guard assembly 22, and a post 36 for joining the needle

guard assembly 22 sections together. Said post 36 is received by a corresponding slot or opening 37 (shown as a dotted line).

Figure 73 is a full rear view of the needle guard assembly 22 shown in an open-faced configuration comprising a needle guard assembly 22 having a hinge section 28 joining each section, said hinge section 28 having a slot or recess for inserting a fixedly attached, separate tether (not shown), said hinge section 28 also having a fin 79 being hingedly attached to said hinge section 28, said fin 79 being bendable over said hinge section 28 for fixedly attaching a separate tether by a heat weld or press means, said needle guard 22 having a split line 43 where the needle guard 22 sections mate or join together, an aperture guide 34 on each needle guard 22 section, a protrusion 98b for joining with the corresponding element 98b on the alternate needle guard assembly 22 section, a moveable needle trap 41, at least one post or protrusion 36 on one needle guard assembly 22 section which enters at least one corresponding slot 37 on the other needle guard assembly 22 section for securing the sections together. Said post 36 is received by a corresponding slot or opening 37 (shown as a dotted line).

Figure 74 is a full, inside face view of one half of the needle guard assembly 22 containing the elements shown and described in Figure 71 showing said needle guard 22 in its molded configuration comprising a foldable, open-faced needle guard 22 having a hinge section 28 for attaching a separate tether with adjacent lands 39 which create an aperture when said needle guard assembly 22 is coupled together, a slot or void 25 is created when the needle guard 22 sections are joined together, a distal guide section 47 is also

created when the needle guard 22 sections are joined together, said needle guard 22 having a corresponding slot or opening 31 for receiving said needle trap 41 (see Figure 71), said needle trap having at least one pin 36 (see Figure 71) and a corresponding opening 37 for frictionally engaging said needle guard 22 sections together about the hypodermic needle, said pin 36 and slot 37 (see Figure 71) can be positioned on either side of needle guard 22 sections, said needle guard 22 having an internal guide section 35 and a proximal guide section 34 with a void or space 38 between said guides 34 and 35, said needle trap having an internal landing 52 located between said internal guide 35, with said landing 52 having an adjacent landing 53 which serves to guide said hypodermic needle during assembly, storage and use, said landing 53 also houses said sharpened needle tip within said needle guard 22. Said needle guard 22 being fixedly attached to a separate tether (not shown) at hinge section 28.

Figure 75 is a cross sectional view of the needle guard 22 in Figure 71 shown in axis 75-75 comprising a needle guard 22, a movable needle trap 41 and fins or skirts 46. Said skirts 46 maintain alignment of the trapped sharpened needle tip within said needle trap 41.

Figure 76 is a cross sectional view of the needle guard 22 in Figure 71 shown in axis 76-76 comprising a needle guard 22, a split line 43, a slot 37 and a landing 53.

Figure 77 is a cross sectional view of the needle guard 22 in Figure 74 shown in axis 77-77 comprising a needle guard 22, a split line 43, a guide section 35, said guide section 35 having chamfered or angled ends for aligning a hypodermic needle within said guide

section 35 on said needle guard 22 during the assembly procedure, said hypodermic needle 10 (shown in other drawings in this application) resides adjacent to the landing 52.

Figure 78 is a cross sectional side view of a hypodermic needle for use on a male luer syringe in a ready for use state in accordance with one embodiment of the present invention. The needle assembly is contained within a protective storage cover 54 and end cap 68, whereby needle 10, needle guard 22, resilient member 19, tether 24, hub 12 and flange 16 are held within said cover 54 by a wedging action of said flange 16 with the cover 54. Figure 78 further illustrates a hub 12, a fixedly attached needle 10, a means for retaining a separate, movable needle guard 22, said needle guard 22 having an aperture therethrough for said hypodermic needle 10, whereby the needle guard 22 is retained in a ready to use position on said hub 12, with said retained needle guard 22 being urged away from said needle hub 12 by a compressed resilient member 19, said resilient member 19 being located between, among or amid said hub 12 and said needle guard 22, said resilient member 19 also being located in an annular fashion about or surrounding a portion of said needle guard 22, said needle guard 22 is fixedly attached to said needle hub portion 15 by means of a limiting tether 24

Said hub 12 having an aperture therethrough creating a fluid/gas path to said hypodermic needle 10, at least one flange 101 for attaching the needle hub 12 to a male luer fitting, a needle nest 4 for fixedly attaching the needle 10, said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said needle nest 4, and an integral hub portion 15

having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected to the hub portion 15, said hub portion 15 having a fixedly attached tether 24, said hub portion 15 also having a section 16 for removably attaching said protective storage cover 54, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably held position adjacent or on said hub portion 15, said latching arm 26 also having a protrusion 49 for biasing the latching arm 26 in an outward manner when a compressive force is applied to said releasably held needle guard 22, said movable needle guard 22 having a proximal guide section 34, an internal guide section 35, with a recess or void 38 residing between said proximal guide section 34 and said internal guide section 35, a distal needle guard guide aperture 47, a receiving slot 31 to receive the needle trap 41 (not shown) a retaining area 44a with an aperture 48 to receive said protrusion 21, said needle guard 22 having a compressed resilient member 19 positioned at the proximal end of said needle guard 22 said with the resilient member 19 exerting an extending force on said needle guard 22; with said needle guard 22 being releasable held in a compressed position by the hook 21 of the moveable latching arm 26 on said hub portion 15, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 12, said aperture having the hub protrusion 5 positioned therethrough, said latching arm 26 having a protrusion 49 for engaging said needle guard assembly 22 when said needle guard 22 is urged toward said hub portion 12, said needle guard 22 engages

protrusion 49 and mechanically urges said latching arm 26 in an outward manner ensuring said latching arm 26 moves outwardly releasing the hold on the needle guard assembly 22.

Said cover 54 having at least one internal projection 56, said projection holding said needle guard 22 and resilient member 19 in a retracted state during storage and prior to use, said cover 54 having a projection 55 for biasly holding or wedging said latching arm 26 in a retaining manner, said latching arm 26 releasably holding said needle guard 22 and said resilient member 19 in a retained position prior to use. The diameter of said cover 54 could also be sized to biasly hold said latching arm 26 in a retaining manner, therefore, eliminating the need for said projection 55.

A cap 68 is removably placed into or on said cover 54 to contain said needle assembly within said cover 54 and said cap 68, said cap 68 having a plurality of square shoulders 69, and a wall section 70 removably sealing said cover 54 and said cap 68 together at the tortuous path interface 71 maintaining a sterile field within said cover 54 and cap 68. Said projection 56 relieves the extending force of said resilient member 19 on said releasably held needle guard 22, said retaining latching arm 26 and said hinge 23 of said latching arm 26, by slightly compressing said resilient member 19, while said projection 55 holds said latching arm 26 in a wedged or confined position whereby said needle guard 22 is releasably held by said latching arm 26 when said cover 54 is removed from said needle assembly.

Figure 79 is a cross sectional side view of the invention comprising a hypodermic needle for use on a pre-filled syringe or

pre-filled cartridge syringe in a ready for use state having a needle guard 22 and hypodermic needle 10 being stored and retained in a protective storage cover 54, showing a full view of said hypodermic needle 10, said cover 54 having a means for retaining a separate, movable needle guard 22, said needle guard 22 having an aperture therethrough for said hypodermic needle 10, said needle 10 having a distal sharpened end 11, whereby the needle guard 22 is retained in a ready to use position, with said retained needle guard 22 being urged away from said prefilled syringe by a compressed resilient member 19, said resilient member 19 being located between, among or amid said prefilled syringe and said needle guard 22, said resilient member also being located in an annular fashion about or surrounding a portion of said needle guard 22, said needle guard 22 is fixedly attached to said needle hub portion 15 by means of a limiting tether 24.

Said integral hub portion 15 having a protrusion 5 located at the distal end of said hub portion 15, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably held position adjacent to or on said hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to said releasably held needle guard 22, said movable needle guard 22 having a proximal guide section 34, an internal guide section 35, a space or recess 38 between said proximal guide 34 and internal guide 35,

a distal needle guard guide aperture 47, a receiving slot 31 to receive a needle trap 41 (not shown), a retaining area 44a with an aperture 48 to receive said protrusion 21, said needle guard 22 having a compressed resilient member 19 positioned at the proximal end of said needle guard 22 said with the resilient member 19 exerting an extending force on said needle guard 22; with said needle guard 22 being releasable held in a compressed position by the hook 21 of said moveable latching arm 26 on said hub portion 15, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 12, said aperture having the hub protrusion 5 positioned therethrough, said latching arm 26 having a protrusion 49 for engaging said needle guard assembly 22 when said needle guard 22 is urged toward said pre-filled syringe, said needle guard 22 engages protrusion 49 and mechanically urges said latching arm 26 in an outward manner ensuring said latching arm 26 moves outwardly releasing the hold on the needle guard assembly 22.

Said cover 54 having a soft elastomeric or rubber seal 72 inside or within the closed end of said cover 54 which sealingly engages said sharpened tip 11 and said needle 10 of a pre-filled syringe or pre-filled cartridge against leakage.

Figure 80 is a cross sectional view of the hub 12 contained within a storage cover 54 in axis 80-80 of Figure 78 and comprising a hub section 12, a storage cover 54 having at least one vane 57 for gripping a flange shoulder of said hub 12 so the needle 10, said hub 12 and said needle guard 22 can be safely turned or twistedly attached with the cover 54 on or off a medical device.

Figure 81 is a cross sectional view of the needle 10 contained within a cover 54 in axis 81-81 of Figure 79. Cover 54 includes at least one, or a plurality of internal projections 73, said projections 73 relieve the extending force of said resilient member 19 on said releasably held needle guard 22, said retaining latching arm 26 and said hinge 23 of said latching arm 26, by slightly compressing said resilient member 19 during storage.

Figure 82 is a full front view of an open collar or washer 30 used with the indwelling I.V. catheter embodiment of the invention, said washer 30 retaining the resilient member 19 on the proximal end of the needle guard 22a on said catheter assembly shown in Figures 62, 63, and 64. Said washer having an angled entrance 63 for engaging said washer onto said needle guard 22a . Said washer 30 could comprise a flat configuration and be inserted into a corresponding slot on said needle guard 22a to hold said resilient member 19 on said needle guard 22a.

Figure 83 is a cross sectional view of the washer 30 shown in along axis 83-83 in Figure 82.

Figure 84 is a cross sectional top view of the invention containing the elements shown and described in Figure 64 having a movable metal needle trap 41 used to trap the sharpened needle tip 11 within said needle guard 22, comprising a hub 12 at least one proximal flange 101, a hub portion 15 and a flange 16 for wedgedly and removably attaching a protective cover, a releasably held needle guard assembly 22 being releasably held adjacent to said hub portion 15, said guard assembly 22 being movable by the stored energy present in the compressed resilient member 19, said resilient

member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said metal needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19, said needle guard 22 having a proximal guide section 34, a distal needle guide aperture 47, a metal needle trap 41 biasly contacting said hypodermic needle 10 by the inherent memory of the metal configuration of said needle trap 41 and/or the extending force of the surrounding resilient member 19, whereby the advancing movement of said needle guard 22 is limited by a fixedly attached tether (not shown), said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12. Said needle trap 41 being hingedly inserted to said needle guard 22 at a hinge slot 40, said needle guard 22 having a receiving slot 31 to receive the needle trap 41, a distal needle guide aperture 47, said needle trap 41 having skirts 46 (shown in Figure 75) to retain said sharpened needle end 11 within said metal needle trap 41.

Said needle trap 41 being insertable onto said needle guard 22 from the outside of said needle guard, allowing said needle trap 41 to be inserted onto said needle guard 22 either before or after said needle guard 22 is clasped around said hypodermic needle 10 from the side during assembly procedures.

Figure 85 is a cross sectional top view of the invention containing the elements shown and described in Figures 64 and 84 having a movable metal needle trap 41 used to trap the sharpened

needle tip 11 within said needle guard 22, comprising a hub 12 at least one proximal flange 101, a hub portion 15 and a flange 16 for wedgedly and removably attaching a protective cover, a releasably held needle guard assembly 22 being releasably held adjacent to said hub portion 15, said guard assembly 22 being movable by the stored energy present in the compressed resilient member 19, said resilient member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said metal needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19, said needle guard 22 having a proximal guide section 34, a distal needle guide aperture 47, a metal needle trap 41 biasly contacting said hypodermic needle 10 by the inherent memory of the metal configuration of said needle trap 41 and/or the extending force of the surrounding resilient member 19, whereby the advancing movement of said needle guard 22 is limited by a fixedly attached tether (not shown), said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12. Said needle trap 41 being hingedly inserted to said needle guard 22 at a hinge slot 40d, said needle guard 22 having a receiving slot 31 to receive the needle trap 41, a distal needle guide aperture 47, a receiving slot 31 to receive the metal needle trap 41, said needle trap 41 having skirts 46 (shown in Figure 75) to retain said sharpened needle end 11 within said metal needle trap 41.

Said needle trap 41 being insertable onto said needle guard 22 from the inside of said needle guard, allowing said needle trap 41 to be inserted onto said needle guard 22 before said needle guard 22 is clasped around said hypodermic needle 10 from the side during assembly procedures.

Figure 86 is a graph depicting the interaction of a resilient member and a sliding member, said sliding member being on an elongated shaft, said sliding member having a movable arm being urged away from said resilient member by an extending force, said moveable arm being movably wedged between the diameter of said resilient member and said shaft, said arm slidably contacting said shaft, and where another area of said resilient member is positioned around said sliding member, said resilient member being releasably retained by said movable arm on said sliding member, said resilient member having a portion of said sliding member within said resilient member's inside diameter, whereby the binding force of said resilient member on said sliding member and said movable arm eventually exceeds the extending force of said resilient member as said resilient member extends. Said extending force of said resilient member is greatest when said resilient member is completely compressed, and conversely, said extending force of said resilient member is weakest when said resilient member is completely elongated. The binding force of said resilient member on said movable arm is greatest when said resilient member is compressed.

Figure 87 is a graph depicting the interaction of a resilient member and a sliding member, said sliding member being on an elongated shaft, said sliding member having a movable arm being

urged away from said resilient member by an extending force, said moveable arm being movably wedged between the diameter of said resilient member and said shaft, said arm slidably contacting said shaft, and where another area of said resilient member is positioned in a notch or recess on said sliding member, said resilient member being releasably retained by said movable arm and said notch on said sliding member, said resilient member having a portion of said sliding member within said resilient member's inside diameter, whereby the binding force of said resilient member on said sliding member and said movable arm is always less than the extending force of said resilient member as said resilient member extends. Said extending force of said resilient member is exerted in the land created by said notch, maintaining a greater extending force on said sliding member and said movable arm than said binding force of said resilient member. Said movable arm is urged inwardly from a retaining position when said sliding member advances beyond the end of said shaft, thereby releasing the hold on said resilient member.

Figure 88 is a cross-sectional side view of the present invention ready for use on a male luer syringe showing a full view of the hypodermic needle 10, and a cross sectional view of the releasing means shown and described in Figure 48A comprising a hub 412 with a fixedly attached needle 10, a means for retaining a separate, movable needle guard 22, said needle guard 22 having an aperture therethrough for said hypodermic needle 10, whereby the needle guard 22 is retained in a ready to use position on said hub 412, with said retained needle guard 22 being urged away from said needle

hub 412 by a compressed resilient member 19, said resilient member 19 being located between, among or amid said hub 412 and said needle guard 22, said resilient member 19 also being located in an annular fashion surrounding a portion of said needle guard 22, said needle guard 22 is fixedly attached to said needle hub portion 215 by means of a limiting tether 24.

Said needle guard 22 having a retaining means 77, said retaining means having an aperture 78 for releasably holding said needle guard 22 in a retained position adjacent to said hub portion 215, said needle guard 22 having a latching arm 81 being hingedly attached to said needle guard 22 at a hinge section 23, a protrusion 49 for urging said arm 81 from a releasably held position adjacent to said hub portion 215 when a compressive force is applied to said needle guard 22 and said protrusion 49 engages said retaining means 77 and mechanically releases said hold on said needle guard 22, said arm 81 having a protrusion 21 for releasably holding said arm 81 in said aperture 78 of said retaining means 77, said arm 81 having a finger pad 27 with projections which do not impede the movement of said pad 27 and said protrusion 21 through said aperture 78 as said needle guard 22 is urged away from said hub portion 215.

Said hub 412 having an aperture therethrough creating a fluid/gas path to said hypodermic needle 10, at least one flange 101 for attaching the hub 412 to a male luer fitting, a needle nest 4 for fixedly attaching the needle 10, said needle 10 a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 412 and an integral hub portion 215 having a protrusion 5 located at the distal end of said hub portion 215, said protrusion 5

being connected to the hub portion 215, said protrusion 5 having a fixedly attached tether 24, said hub portion 215 also having a section 16 for removably attaching a protective storage cover said movable needle guard 22 having a proximal guide section 34, an internal guide section 35, with a recess or void 38 residing between said proximal guide section 34 and said internal guide section 35, a distal needle guide aperture 47, a receiving slot 31 to receive the needle trap 41 said needle guard 22 having a compressed resilient member 19 positioned at the proximal end of said needle guard 22 said with the resilient member 19 exerting an extending force on said needle guard 22; with said needle guard 22 being releasably held in a compressed position by the hook 21 of the moveable latching arm 81 on said needle guard 22, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 215, said aperture having the hub protrusion 5 positioned therethrough, said latching arm 81 having a protrusion 49 for engaging said retaining means 77 when said needle guard 22 is urged toward said hub portion 215, said needle guard 22 engages protrusion 49 and manually moves said latching arm 81 in an outward manner ensuring said latching arm 81 moves inwardly releasing the hold on the needle guard assembly 22.

Figures 89, 90 and 91 show a cross-section view of the invention described in Figures 84, 85 and 88, respectively, wherein hub 212 includes a threaded section 74 for attaching the hub to a blood collection device. (See Figure 25.)

Figures 92, 93 and 94 show a cross-section view of the invention described in Figures 84, 85 and 88, respectively, being fixedly attached to a prefilled syringe.

Figure 95 is a full side view drawing of the disclosed invention hub component 12, comprising a hypodermic needle hub 12 with a flange 101 for attaching the needle hub 12 to a male luer fitting, a needle nest 4, a section 16 for removably holding a protective storage cover over a hypodermic needle (not shown) a protrusion 5 located at the distal end of the hub portion 15, said hub portion 15 having at least one aperture 89 for inserting a glue carrying fixture or the like to apply glue to the needle during assembly, said aperture 89 also being a venting means to allow pneumatic pressure to escape during insertion of needle 10 with glue into said needle nest 4, said protrusion 5 being connected to the hub portion 15 at the distal end of the hub portion 15, said section 16 having a shoulder 14 for twistedly attaching said invention to a storage cover, and a moveable latching arm 26 with a finger pad 27, attached to the hub portion 15 by a hinge section 23, said finger pad 27 having at least one protrusion for creating a more positive grip or contact with said finger pad 27, said finger pad 27 also comprising a different, or bright color, which serves as a visual indicator for the user to easily locate the finger pad 27 for manual release of a needle guard assembly or the like, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position adjacent to said hub portion 15, said moveable latching arm 26 shown in the preferred molded position.

Figure 96 is a full side view drawing of the disclosed invention hub component 12, comprising a hypodermic needle hub 12 with a flange 101 for attaching the needle hub 12 to a male luer fitting, a needle nest 4, a section 16 for removably holding a protective

storage cover over the hypodermic needle (not shown), a protrusion 5 located at the distal end of the hub portion 15, said hub portion 15 having at least one aperture 89 for inserting a glue carrying fixture or the like to apply glue to said needle 10 during assembly, said aperture 89 also being a vent to allow pneumatic pressure to escape during insertion of needle 10 into said needle nest 4, said protrusion 5 being connected to the hub portion 15 at the distal end of the hub portion 15, said section 16 having a shoulder 14 for twistedly attaching said invention to a storage cover, and a moveable latching arm 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position adjacent to said hub portion 15, said moveable latching arm 26 shown in the preferred molded position.

Figure 97 is a cross-sectional side view of the invention attached to a prior art glass pre-filled syringe 6 having a nest bead 7 and a hypodermic needle 10 with a distal sharpened end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard 22 relative to the needle tip 11 after positioning the needle guard at the distal end of the needle 10. Figure 97 further shows a hub body 15 being fixedly attached to said syringe 6 at the nest bead 7 by the attaching section 65; said hub body 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub body 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub body 15 by a

hinge section 23, said lever 26 having a touch pad 27, a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22 (shown in other drawings in this application), with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub portion 15.

Figure 98 is a cross-sectional side view of the invention integrally molded to a pre-filled cartridge syringe hub 8b having a fixedly attached needle 10 with a sharpened proximal end 111 and a sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard relative to the needle tip 11 after positioning said needle guard at the distal end of the needle 10, said sharpened proximal end 111 is for piercing the stopper of a medicine or fluid cartridge. The invention includes an integral hub portion 15, having a needle nest 4; said hub portion 15 having a protrusion 5 located on said hub portion 15, said hub portion 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging the latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22 with said moveable

latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub portion.

Figure 99 is a cross-sectional side view of the invention attached to a prior art pre-filled cartridge syringe hub 8a having a fixedly attached needle 10 with a sharpened proximal end 111 and a sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard (not shown) relative to the needle tip 11 after positioning a needle guard at the distal end of the needle 10, said sharpened proximal end 111 for piercing the stopper of a medicine or fluid cartridge. The invention includes a hub portion 15 being fixedly attached to said syringe hub 8a at the needle nest 4; said hub portion 15 having a protrusion 5 located on said hub portion 15, said hub portion 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably held position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging the latching arm 26 in an outward manner when a compressive force is applied to a releasably held needle guard, with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub body 15.

Figure 100A is a cross-sectional side view an I.V. catheter introducer having a hub section 9, having a fixedly attached needle 10 with a sharpened distal end, said needle 10 having a change in

profile 3 near the distal end for limiting axial movement of a slidable needle guard (not shown) relative to the needle tip 11 after positioning said needle guard 22 at the distal end of the needle 10, a section 18 for removably attaching a protective storage cover, a hypodermic needle 10 being fixedly attached to a needle nest 4; said catheter mounting section 9 being retrofitted with the present invention, wherein hub portion 15 is fixedly attached to said catheter mounting section 9 at the nest 4 by the attaching section 66, said hub portion 15 also having a section 16 for removably attaching a protective storage cover.

Figure 100B is a cross-sectional side view of the present invention integrally molded to an I.V. catheter introducer comprising a hub 9, a hypodermic needle 10 being fixedly attached to a needle nest 4 said needle 10 having a sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard (not shown) relative to the needle tip 11 after positioning said needle guard 22 at the distal end of the needle 10, a hub portion 15, said hub portion 15 having a protrusion 5 located on said hub portion 15, said hub body 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard with said moveable latching arm shown in the preferred

position for retaining at least one component in a retained position on the hub portion 15.

Figure 101 is a cross sectional side view of the invention being threadedly attached to a glass cartridge hub 68, said glass cartridge hub 68 being fixedly attached to a glass cartridge 6, said hub 68 having a needle nest 4 for fixedly attaching a needle 10, said needle 10 having a sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard relative to the needle tip 11 after positioning said needle guard 22 at the distal end of the needle 10, said hub 68 also having a threaded section 67 fixedly attaching hub body is to said glass cartridge hub 68 by the threaded section 67; said hub body 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub body 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub body 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22 (shown in other drawings in this application), with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub body 15.

Figure 102 is a cross sectional side view of the invention being fixedly attached to a glass cartridge 6, comprising a hub 68 having a

needle nest 4 for fixedly attaching a needle 10, said needle 10 having a sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end for limiting axial movement of a slidable needle guard relative to the needle tip 11 after positioning said needle guard 22 at the distal end of the needle 10, a hub portion 15 being integrally molded to said glass cartridge hub 69; said hub portion 15 having a protrusion 5 located at the distal end of said hub portion 15, said protrusion 5 being connected at the distal end of the hub portion 15, said hub body 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasable position on the hub portion 15, said latching arm 26 also having a protrusion 49 for urging said latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22 (shown in other drawings in this application), with said moveable latching arm 26 shown in the preferred position for retaining at least one component in a retained position on the hub body 15.

Figure 103 is a cross sectional top view of the invention shown on an indwelling catheter 29 embodiment, having a movable needle guard 22a and a separable indwelling I.V. catheter 29, said catheter 29 being fixedly attached to a catheter hub 13; a hub 9 having a fixedly attached hollow bore hypodermic needle 10 having a sharpened distal end 11, said needle 10 being fixedly attached to a hub portion 15 having a section 16 for removably attaching a protective storage cover, a slidable needle guard 22a being fixedly

attached to said hub portion 15 by means of a limiting tether 24, said tether 24 being slidably disposed through an aperture on said hub 9, said needle guard 22a having a projection or finger post 80 for advancing said separable catheter 29 and said needle guard 22a along said hypodermic needle 10 so said catheter 29 may be inserted into a blood vessel, said hypodermic needle 10 being slidable through a guide aperture in said movable needle guard 22a, said needle guard 22a having a movable needle trap 41 with a corresponding slot 31 for receiving the needle trap 41 when said trap 41 moves beyond the needle tip 11, said needle guard 22a having an open collar or washer 30 for retaining the resilient member 19 on the proximal end of said needle guard 22a, said resilient member 19 being slidably held on said needle guard 22a by the notch or indentation 60, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22a into notches 60 and/or 61, said needle trap 41 also having a notch or indentation 61 for retaining said end coils of said resilient member 19, with the distal end of said needle guard 22a having a male section 78 for removably attaching an indwelling I.V. catheter hub 13, said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said male section 78 after insertion of the catheter 29 into a patient. Said catheter hub 13 having at least one flange 301 and an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 42. Said movable arm 42 could also comprise a metal component which is inserted during or after said male section 78 is manufactured.

Said channel 32 can comprise an annular, or segmented configuration.

Said hub portion 15 could also comprise the latching arm 26 shown in other drawings in this application, otherwise said needle guard 22a would be releasably held adjacent to said hub portion 15 prior to use by a frictional or wedged means. The disclosed invention is shown in a ready to use state in Figure 103.

Figure 104 is a cross sectional top view of the invention shown showing the catheter introducer needle tip 11 being withdrawn into the needle guard 22a. The catheter 29 and catheter hub 13 remain releasably held adjacent to said needle guard 22a as the needle 10 is being withdrawn from the catheter insertion site through the distal guide 47 of said needle guard 22a. This drawing shows said needle guard 22a being held within a housing or shroud 85. Said housing 85 having an inner chamber for receiving a resilient member 19 and a slidable needle guard 22a, said housing 85 also having exterior projections 86 serving as a non-slip gripping means, said projections 86 can be longitudinal, radial or the like, and may comprise any surface or contour which improves the hold by the user on said housing 85. Said housing 85 may also have an internal projection 88 for fixedly attaching said needle guard 22a within said housing 85, and internal fins 97 to concentrically locate said resilient member 19 within said housing 85. Said needle guard 22a being held within said housing 85 by a snap-fit means created by the wedge 66a and slot 66b at the proximal end of said needle guard 22a. Said housing 85 having a corresponding aperture to receive said wedge 66a and slot 66b, said aperture having a "lead-in" 96 for easy assembly of said

guard 22a into said housing 85. Said housing also may have an internal ring or at least one projection 88 which correspondingly is received by a slot 89 in said needle guard 22a. Said slot 89 and projection 88 may be placed either on the guard 22a or housing 85.

Said slidable needle guard 22a being fixedly attached to a hub portion by means of a limiting tether 24, said hypodermic needle 10 being slidable through a proximal guide aperture 34 in said movable needle guard 22a, said needle guard 22a having a movable needle trap 41 with a corresponding slot 31 for receiving the needle trap 41 when said trap 41 moves beyond the needle tip 11, said needle guard 22a having a notch or indentation 60 for releasably holding said resilient member 19 on said needle guard 22a, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22a into notches 60 and/or 61, said needle trap 41 also having a notch or indentation 61 for retaining said end coils of said resilient member 19, with the distal end of said needle guard 22a having a male section 78 for removably attaching an indwelling I.V. catheter hub 13, said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said male section 78 after insertion of the catheter 29 into a patient. Said catheter hub 13 having at least one flange 301 and an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 45 and said projection 42. Said movable arm 45 could also comprise a metal component which is inserted during or after said male section 78 is manufactured.

Said hub portion 15 could also comprise the latching arm 26 shown in other drawings in this application, otherwise said needle

guard 22a would be releasably held adjacent to said hub portion prior to use by a frictional or wedged means.

Figure 105 is a cross sectional and cut away top view of the movable needle guard 22a on an indwelling catheter 29 embodiment containing the elements shown and described in Figure 104, showing the needle tip 11 being safely contained within the needle guard 22a with the arm 45 and projection 42 correspondingly moved inwardly and activated with the needle trap 41, including a few different versions of the components: said tether 24 being fixedly attached to the housing 85, said housing 85 having at least one longitudinal non-slip projection 86, said housing having a distal projection 90 which may snap over said needle guard 22a when said needle guard 22a is contained within said housing 85, said needle guard 22a having a split line 43, said projection 42 having a "v" shape. The shape of the projection 42 is not limited to a singular or double faced surface, but might be oval, round, radial, smooth or rough or a combination of any surfaces described herein.

Figure 106 is a cross-sectional and cut away side view of the present invention ready for use on a male luer syringe shows a full view of the hypodermic needle 10 having a change in profile 3 near the distal end for limiting axially movement of a slidable needle guard 22 relative to the needle tip 11 after positioning said needle guard 22 at the distal end of the needle 10 comprising: a hub 12 with a fixedly attached needle 10, a means for retaining a separate, movable needle guard 22, said needle guard 22 having an aperture therethrough for said hypodermic needle 10, whereby the needle guard 22 is retained in a ready to use position on said hub 12, with

said retained needle guard 22 being urged away from said needle hub 12 by a compressed resilient member 19, said resilient member 19 being located between, among or amid said hub 12 and said needle guard 22, said resilient member 19 also being located in an annular fashion surrounding a portion of said needle guard 22.

Said hub 12 having an aperture therethrough creating a fluid/gas path to said hypodermic needle 10, at least one flange 101 for attaching the needle hub 12 to a male luer fitting, a needle nest 4 for fixedly attaching the needle 10, said needle 10 a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12 and an integral hub portion 15 having a protrusion 5 located at the distal end of said hub body 15, said protrusion 5 being connected to the hub portion 15, said hub portion 15 also having a section 16 for removably attaching a protective storage cover, a moveable latching arm or lever 26 with a touch pad 27 attached to the hub portion 15 by a hinge section 23, with the moveable latching arm 26 having a protrusion 21 for retaining a component in a releasably retained position on the hub portion 15, said latching arm 26 also having a protrusion 49 for biasing the latching arm 26 in an outward manner when a compressive force is applied to the releasably held needle guard 22; and a movable needle guard 22 having a proximal guide section 34, a distal needle guide section 47 and a movable needle trap 41 (not shown in this view), a receiving slot 31 to receive the needle trap, a retaining area 44a with an aperture 48 to receive said protrusion 21, said needle guard 22 having a compressed resilient member 19 positioned at the proximal end of said needle guard 22 said with the resilient member 19

exerting an extending force on said needle guard 22; with said needle guard 22 being releasably held in a compressed position by the hook 21 of the moveable latching arm 26 on said hub portion 15, an aperture for orienting said needle guard assembly 22 adjacent to said hub portion 12, said aperture having the hub protrusion 5 positioned therethrough, said latching arm 26 having a protrusion 49 for engaging said needle guard 22 when said needle guard 22 is urged toward said hub portion 12, said needle guard 22 engages protrusion 49 and manually moves said latching arm 26 in an outward manner ensuring said latching arm 26 moves outwardly releasing the hold on the needle guard 22.

Figure 107 is a cross sectional and cut away top view of Figure 106 containing the elements shown and described in Figure 106 with the releasably held needle guard assembly 22 (shown in a partial cut away view) being releasably held adjacent to said hub portion 15, said guard assembly 22 being movable by the stored energy present in the compressed resilient member 19, said resilient member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19, said needle guard 22 having a proximal guide section 34, a distal needle guide aperture 47, a needle trap 41 biasly contacting said hypodermic needle 10 by the inherent memory of the molded configuration of said needle trap 41 and/or the extending force of the surrounding resilient member 19, whereby the

advancing movement of said needle guard 22 is limited by a change in profile 3 of said needle 10, said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12.

Said needle 10 being fixedly attached to hub 12 in a needle nest 4, said hub 12 having a flange 16 for removably attaching a protective cover, and at least one flange 101. Said needle trap 41 being hingedly attached to said needle guard 22 by a hinge section 40, said needle guard 22 having a receiving slot 31 to receive the needle trap 41.

Figure 108 is a cross sectional and cut away top view Figures 106 and 107 showing the needle tip 11 being trapped within the needle guard 22 by the movable needle guard 41, comprising a hypodermic needle 10 having a sharpened tip 11, said needle guard 22 being limited in its axial movement by means of a change in profile 3 near the distal end of said needle 10, with the resilient member 19 extended and maintaining an extending force on the needle guard assembly 22, said needle guard 22 is prevented from advancing further by the limiting feature of said change in profile 3, said resilient member 19 being slidably retained on said needle guard 22 by the notch or indentation 60, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22 into notches 60 and/or 61, said needle trap 41 also having at least one notch or indentation 61 for releasably retaining said end coils of said resilient member 19, said needle guard 22 having a proximal guide section 34, a distal needle guide aperture 47, a needle trap 41 biasly contacting said hypodermic

needle 10 by the inherent memory of the molded configuration of said needle trap 41 and/or the extending force of the surrounding resilient member 19, whereby the advancing movement of said needle guard 22 is limited by a change in profile 3 of said needle 10, said needle 10 having a sharpened distal end 11 and an unsharpened proximal end being fixedly attached to said hub 12. Said needle 10 being fixedly attached to hub 12 in a needle nest 4, said hub 12 having a flange 16 for removably attaching a protective cover, and at least one flange 101. Said needle trap 41 being hingedly attached to said needle guard 22 by a hinge section 40, said needle guard 22 having a receiving slot 31 to receive the needle trap 41.

Said proximal guide 34 is shown here maintaining the needle guard 22 in a substantially concentric manner on said hypodermic needle 10. Said needle guard 41 also having a tapered or reducing proximal section 304 for non-binding access by the movable resilient member 19.

Figure 109 is a full top view of a needle guard 22 having a proximal guide section 34, a reducing section 304, a longitudinally shaped chamber 94, a projection 63 to allow free movement of a movable latch, and a distal guide section 47. This embodiment utilizes a separate needle guard component.

Figure 110 is a full front view of a needle guard 22 shown in Figure 109, having a longitudinal chamber 94, a slot 25 to accept a latching means, a distal guide section 47, and an aperture.

Figure 111 is a cross sectional view of the needle guard 22 shown in Figure 109 along axis 111-111 showing the slotted configuration, of chamber 94.

Figure 112 is a full bottom view of a needle guard 22 shown in Figure 109 having a notch 60, a reducing section 304 and a projection 63 to allow free movement of a movable latch.

Figure 113 is a full rear view of the movable needle guard 22 shown in Figure 112 having a chamber 94, an aperture, a notch 60 and a proximal guide section 34.

Figure 114 is a full top view of the needle guard 220 for a catheter introducer having an inner chamber 94, a proximal guide section 34, a recess 31 .to receive a movable needle trap, a middle guide section 93 for locating a needle 10 during assembly procedures, a slot 80 for receiving the proximal end of a separate needle trap 41, a slotted catheter adapter 78, a distal guide section 92, and a projection 91 for releasably holding a catheter hub 13 in a specific orientation on said needle guard 220.

Figure 115 is a full front view of the needle guard 220 for a catheter introducer shown in Figure 114 having a middle guide section 93 for locating a needle 10 during assembly procedures, a slotted catheter adapter 78, a distal guide section 92, and a projection 91 for releasably holding a catheter hub 13 in a specific orientation on said needle guard 220. Said needle guard 220 having a needle 10 therethrough, said needle being contained through said needle guard 220 by the separately attached needle trap 41. Said needle 10 being concentrically located through said needle guard 220 located by the needle trap 41.

Figure 116 is a cross sectional and cut away side view of a separate needle trap 41 having a proximal side 82 which inserts into a slot within a slidable needle guard. Needle trap 41 includes a least

one projection 83 for fixedly attaching said needle trap in a needle guard, a lead in side 33 for locating a resilient member during assembly procedures, a notch 61 for maintaining an extending force of said resilient member on said trap 41, and a plurality of sides or skirts 46 to contain a sharpened tip 11 of a needle 10 within said trap 41. Said needle trap 41 can comprise plastic, metal, or any other substantially impenetrable material.

Figure 117 is a full top view of the housing 85 having a lip 90 and internal fins 97. Said fins 97 can be eliminated by shaping the cross section of said housing 85 to match the housing shape shown in Figure 120.

Figure 118 is a cross sectional and cut away top view of a catheter introducer comprising the components shown and described in Figure 114, having a needle 10 with one sharpened distal end 11, said needle 10 having a change in profile 3 near the distal end of said needle 10, said needle 10 being fixedly attached to a hub 9 by a needle nest 4, said hub 9 having a flange or plurality of projections 16 to accept a removable storage cover, said needle 10 having a needle guard 220 being slidably disposed about said needle 10 and initially positioned adjacent to the proximal end of said needle 10. Said needle guard 220 having a receiving slot 31 for a movable needle trap 41, a slot 80 for fixedly attaching a separate needle trap 41, a catheter adapter 78, and a proximal guide section 34. Said needle trap 41 having a proximal side 82 which is received in said slot 80, a plurality of sharp projections 83 for fixedly attaching said needle trap 41 on said needle guard 220 into slot 80, an extending arm 45 and a projection 42 for releasably holding a catheter hub 13

adjacent to said needle guard 220, said side 82 having a guide section 84 for locating said needle centrally through said guard 220. Said separable catheter 29 having a hub 13 and an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 42. This embodiment still side loads onto a needle, leaving the delicate tip untouched and sharp.

Figure 119 is a full top view of the separate needle trap 41 for a syringe or blood collecting assembly, comprising a needle trap 41, a plurality of skirts 46, each created by a fold, a notch 61, a lead in section 33, a proximal side 82, created by a fold, having a plurality of sharp projections 83 and a guide section 84. Notch 61 and lead in section 33 are optional.

Figure 120 is a cross sectional and cut away top view of a catheter introducer ready for use comprising the components shown and described throughout this application, having a needle 10 with one sharpened distal end 11, said needle 10 being fixedly attached to a hub 9 by a needle nest, said hub 9 having a lead in area 38 for concentrically locating a movable housing 85 onto said needle 10, a flange or plurality of projections 16 to accept a removable storage cover, said needle 10 having a needle guard 22a being slidably disposed about said needle 10 and initially positioned adjacent to the proximal end of said needle 10. Said hub 9 also having a distal hub section 15 and a flashback chamber located at the distal end of said hub 9. Said flashback chamber being closed by means of a removable plug 100.

This drawing shows said needle guard 22a being held within a housing or shroud 85, said housing having a tapered configuration,

allowing for concentric placement of said resilient member within said housing and an improved gripping means by the user. Said housing 85 having an inner chamber for receiving a resilient member 19 and a slidable needle guard 22a, said housing 85 may also have exterior serrations or channels serving as a non-slip gripping means. Said needle guard 22a being held within said housing 85 by a snap-fit means created by the wedge 66a and slot 66b at the proximal end of said needle guard 22a. Said housing 85 having a curb 90 serving as a gripping means, and a corresponding, proximal aperture to receive said wedge 66a and slot 66b, said aperture having a "lead-in" 96 for easy assembly of said guard 22a into said housing 85.

Said housing 85 and resilient member 19 are assembled onto the needle 10 by an over the needle 10 procedure. The proximal aperture of said housing 85 is substantially larger than the needle 10 diameter, allowing the housing 85 to easily be assembled onto the needle 10 without touching the delicate tip 11. A means to automatically and concentrically locate the housing 85 on the needle 10 is described in this application. The proximal guide section 34 of the needle guard 22a is only slightly larger than the needle 10 diameter, allowing a close, concentric fit necessary for the invention to function properly. The needle guard 22a is loaded onto the needle 10 from the side and once the clam shell guard 22a is closed, the concentrically located needle guard 22a slides down the needle 10 shaft and snap fits into the concentrically located housing 85 and resilient member 19. The side load guard 22a also works in the same concentric manner once the separate needle trap 41 is fixedly

attached to the needle guard 22a once the guard 22a and trap 41 are concentrically located on the needle 10 shaft.

Said needle guard 22a comprising a clam-shell design having a split line 43, a receiving slot 31 for a movable needle trap 41, a distal catheter adapter 78, and a proximal guide section 34 (shown in other drawings in this application). Said needle trap 41 having an extending arm 45 and a projection 42 for releasably holding a catheter hub 13 adjacent to said needle guard 22a. Said separable catheter 29 having a hub 13, an inner channel, recess, slot or undercut 32 for being releasably held by said movable arm 45 and projection 42, and a plurality of flanges 301 to twistedly attach said hub 13 to a luer fitting.

Said slidable needle guard 22a being fixedly attached to a hub portion 9 by means of a limiting tether 24, said tether 24 being fixedly attached to said needle guard 22a by means of an extension 28. Said needle guard 22a having a notch or indentation 60 for releasably holding said resilient member 19 on said needle guard 22a, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22a into notches 60 and/or 61, said needle trap 41 also having a notch or indentation 61 for retaining said end coils of said resilient member 19, with the distal end of said needle guard 22a having a male section 78 for removably attaching an indwelling I.V. catheter hub 13, said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said adapter section 78 after insertion of the catheter 29 into a patient. Said catheter hub 13 having at least one flange 301 and an inner channel, recess, slot

or undercut 32 for being releasably held by said movable arm 45 and said projection 42.

Said needle guard lead in 33 section on said needle trap 41 could also comprise longitudinal channels to reduce the contact surface area of said resilient member, reducing frictional contact and reducing the amount of material used to manufacture the component.

Figure 121 is a cross sectional and cut away top view of a catheter introducer safely trapping the needle tip 11 after the catheter 29 has been inserted into a patient, comprising a needle 10 with one sharpened distal end 11, said needle 10 being fixedly attached to a hub 9 by a needle nest 4, a flange of plurality of projections 16 to accept a removable storage cover, said needle 10 having a needle guard 22a being slidably disposed about said needle 10 and said needle tip 11 being safely positioned within said needle guard 22a. Said hub 9 also having a distal hub section 15 and a flashback chamber located at the distal end of said hub 9. Said flashback chamber being closed by means of a removable plug 100. Said hub 15 having a lead in area 38 for concentrically locating a movable housing 85 onto said needle 10.

Figure 121 shows needle guard 22a being held within a housing or shroud 85 having an integral resilient member 19. Said housing 85 having an inner diameter which locates the compressed resilient member 19 on the notches 60 and/or 61 on said needle guard 22a, said housing 85 may also have exterior serrations or exterior channels serving as a non-slip gripping means, and a proximal skirt 99 which contacts said hub 15 during assembly, allowing said needle guard 22a to be pressed into said housing 85.

Said needle guard 22a being held within said housing 85 by a snap-fit means created by the wedge 66a and slot 66b at the proximal end of said needle guard 22a. Said wedges 66a may have a longitudinal opening 81 at the split line 43 to allow said wedges 66a to compress as said needle guard 22a is snap fit into said housing 85. Said housing 85 may also have a distal curb 90, described in Figure 105, serving as a gripping means, and a corresponding proximal aperture to receive said wedge 66a and slot 66b, said proximal aperture having a "lead-in" 96 for easy assembly of said guard 22a into said housing 85. Said housing 85 is centrally located onto said needle 10 by an over the needle procedure. Said housing 85 having a proximal skirt 99 with an internal annular chamfer for concentrically locating said housing 85 onto said needle 10 and hub 9 by means of chamfered configuration of said needle nest 4. Said skirt 99 is not necessarily needed to implement the present invention.

Said needle guard 22a comprising a clam-shell configuration having a split line 43, a receiving slot 31 for a movable needle trap 41, a distal catheter adapter 78, and a proximal guide section 34 (shown in other drawings in this application). Said needle trap 41 having an extending arm 45 and a projection 42 for releasably holding a catheter hub 13 adjacent to said needle guard 22a. Said separable catheter 29 having a hub 13, undercut 32 for being releasably held by said movable arm 45 and projection 42, and a plurality of flanges 301 to attach said hub 13 to a luer fitting.

Said undercut 32 can be annular or segmented and still provide a holding means to keep said catheter hub 13 adjacent to said needle

guard 22a until said needle tip 11 is fully contained within said needle guard 22a.

Said slidable needle guard 22a being fixedly attached to a hub portion 9 by means of a limiting tether 24, said tether 24 being fixedly attached to said needle guard 22a by means of a extension 28 or the like. Said needle guard 22a having a notch or indentation 60 for releasably holding said resilient member 19 on said needle guard 22a, said movable needle trap 41 having a lead-in area 33 for locating said resilient member 19 on said needle guard 22a into notches 60 and/or 61, said needle trap 41 also having a notch or indentation 61 for retaining said end coils of said resilient member 19, with the distal end of said needle guard 22a having a male section 78 for removably attaching an indwelling I.V. catheter hub 13, said needle trap 41 having a movable arm 45 and projection 42 for releasably retaining a catheter hub 13 from said adapter section 78 after insertion of the catheter 29 into a patient. Said catheter hub 13 having at least one flange 301 and an undercut 32 for being releasably held by said movable arm 45 and said projection 42.

Figures 122A, 122B and 122C show an isometric view of the catheter described in Figures 120 and 121 as the catheter adapter 9 is separated from catheter 29.

Figure 123 is a full top view of the separate needle trap 41 for the indwelling catheter invention, comprising a needle trap 41, a plurality of skirts 46, each created by a fold or bend, a notch 61, a lead in section 33, a proximal side 82, created by a fold or bend, having a plurality of sharp projections 83 and a guide section 84, a ledge, or retainer 27 created by at least one fold or bend, an

extending arm 45, created by a fold or bend, and a projection 42, created by a fold or bend.

Figure 124 is a full and cut away view of Figure 123 comprising a separate needle trap 41 for the indwelling catheter invention, comprising a needle trap 41, a plurality of skirts 46, each created by a fold or bend, a notch 61, a lead in section 33, a proximal side 82, created by a fold or bend, having a plurality of sharp projections 83, a ledge, or retainer 27 created by a fold or bend, an extending arm 45, created by a fold or bend, and a projection 42, created by a fold or bend.

Figure 125 is a is a full, outside, top view of the needle guard assembly 22a for an indwelling catheter shown in its molded configuration comprising a foldable, open-faced needle guard 22a having an extended mounting section 28, a catheter adapter 78, a notch 60 for positioning and maintaining the extending force of a resilient member 19 (not shown) on said needle guard 22a when said guard 22a is in a retained and extending mode, and a wedge 66a and slot 66b at the proximal end of said needle guard 22a. Said needle guard 22a having a movable needle trap 41 being hingedly attached to said needle guard 22a by a hinge 40, said needle trap 41 having an extended arm 45 and projection 42 for releasably retaining a catheter hub from said adapter 78 after insertion of the catheter 29 into a patient. Said needle trap 41 also having at least one notch or multi-level landing 61 for proper positioning of a resilient member 19 (shown in other drawings in this application), said needle trap 41 having a lead in area 33 also for locating said resilient member 19 in a compressed and/or extendible position. Said needle guard 22a

being fixedly attached to a tether 24, said tether 24 having at least one protrusion 20 for fixedly attaching said tether 24 to said hub portion 15 or hub 12, or flange 16.

Figure 126 is a is a full, inside face view of the needle guard assembly 22a for an indwelling catheter shown in its molded configuration comprising a foldable, open-faced needle guard 22a having an extended hinge section 28, a wedge 66a and slot 66b located at the proximal end of said needle guard 22a, said needle guard 22a having a movable needle trap 41 being hingedly attached to said needle guard 22a by a hinge 40, said needle trap 41 having an extended arm 45 and projection 42 for releasably retaining a catheter hub from said adapter 78 after insertion of the catheter into a patient. Said needle guard 22a also having a proximal guide section 34 and a distal guide section 47, which are created when the needle guard 22a sections are joined together, said needle guard 22a also having a middle guide section 93. Said needle guard 22a having a movable needle trap 41 being hingedly attached by the hinge 40, said needle trap 41 having at least one skirt or fin 46 for entrapping said sharpened needle tip 11 (shown in other drawings in this application), said needle guard 22a having a corresponding slot or opening 31 for receiving said needle trap 41, said needle guard 22a having at least one pin 36 and a corresponding opening 37 for frictionally engaging or snap fitting said needle guard 22a sections together about the hypodermic needle 10 (as shown in previous drawings) said pin 36 and slot 37 can be positioned on either side of needle guard 22a sections, said needle guard 22a having an internal guide section 35 and a proximal guide section 34, said needle guard

22a having an internal landing 52 located between said internal guide 35, with said landing 52 having an adjacent landing 53 which serves to guide said hypodermic needle 10 (shown in other drawings in this application) during assembly, storage and use, said landing 53 also houses said sharpened needle tip 11 (shown in other drawings in this application) within said needle guard 22a.

Said needle guard 22a being fixedly attached to an integral, or separate, tether 24. Said tether 24 connects to a hub 15 (not shown).

Figure 127 is a full front view of the clam shell needle guard assembly 22a for an indwelling catheter shown in an open-faced configuration comprising a needle guard assembly 22a having a movable needle trap 41, said needle trap 41 having an extended arm 45 and a projection 42, an internal guide section 35, a distal catheter adapter 78, an extended hinge section 28, with a plurality of needle guard 22a sections connected adjacent to said hinge section 28, said hinge section 28 having an adequate area for insert molding a separate tether or fixedly attaching said separate tether 24, said hinge section 28 also could have an aperture therethrough for fixedly inserting a separate tether 24. Said needle guard 22a having a split line 43 where the needle guard 22a sections mate or join together, an aperture guide 47 on each section at the distal end, and a post 36 for joining the needle guard assembly 22a sections together. Said post 36 is received by a corresponding slot or opening 37 on the adjacent half of said needle guard 22a.

Figure 128 is a full rear view of the needle guard assembly 22a for an indwelling catheter shown in an open-faced configuration comprising a needle guard assembly 22a having an extended hinge

28 for joining each needle guard 22a section together, said extended hinge section 28 having a slot or recess for inserting a fixedly attached, or separate tether (not shown). Said needle guard 22a also having an internal guide section 35, a split line 43 where the needle guard 22a sections mate or join together, a proximal guide 34 and proximal wedge projection 66a located on each needle guard 22a section, a moveable needle trap 41, at least one post or protrusion 36 on one needle guard assembly 22a section which enters at least one corresponding slot 37 on the other needle guard assembly 22a section for securing the sections together. Said post 36 is received by a corresponding slot or opening 37.

Figure 129 is a cross sectional view of the needle guard 22a in Figure 126 shown along axis 129-129 and comprising a needle guard section 22a, an internal guide section 35 having an angled face to concentrically locate said hypodermic needle through said needle guard 22a, a landing 52 and a split line 43.

Figure 130 is a cross sectional view of the disclosed needle guard 22a in Figure 126 shown along axis 130-130 and comprising a needle guard section 22a, and a needle trap 41 having a plurality of skirts or wall sections 46.

A number of embodiments have been disclosed herein as they relate to the needle protective device of the present invention. It is important to understand that many of the elements described herein may be interchangeable. It is also important to note that the invention can comprise a variety of embodiments, ranging from a single piece, injection molded part, where the components are manufactured unitarily, to a plurality of components, all which

achieve the desired result of safely capturing the sharpened needle tip.

WE CLAIM:

1. A needle protective device comprising:

a needle guard slidably mounted on a needle having a sharpened distal end, said needle guard having a proximal end and a distal end, said needle guard containing a movable needle trap that is biased toward said needle, said needle trap entrapping said sharpened distal end of said needle when said distal end of said needle guard moves near said sharpened distal end of said needle; and

limiting means for limiting the forward movement of said needle guard along said needle.

2. The device of claim 1 wherein said needle trap is integral to said needle guard.

3. The device of claim 1 wherein said needle trap is inherently biased toward said needle.

4. The device of claim 1 further comprising biasing means for urging said needle guard forward toward said sharpened distal end of said needle.

5. The device of claim 4 further comprising retaining means for releasably retaining said needle guard near the base of said needle.

6. The device of claim 5 further comprising triggering means for releasing said retaining means.

7. The device of claim 4 wherein said biasing means comprises a resilient member having a proximal end and a distal end.

8. The device of claim 4 wherein the base of said needle is coupled to a housing having a forward end, said needle extending axially from said forward end of said housing.

9. The device of claim 8 wherein said resilient member is disposed between said housing and said needle guard.

10. The device of claim 9 wherein said resilient member comprises a coil spring.

11. The device of claim 5 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said housing, said distal end of said latching arm comprising a protrusion.

12. The device of claim 11 wherein said needle guard includes a recess for receiving said protrusion.

13. The device of claim 11 wherein said latching arm further comprises a finger pad for manually disengaging said latching arm from said needle guard.

14. The device of claim 11 wherein said latching arm comprises a ramp for biasing said latching arm in an outward manner when a compressive force is applied to said needle guard.

15. The device of claim 9 wherein said forward end of said housing comprises an opening, the base of said needle being secured within said opening.

16. The device of claim 15 wherein said housing comprises a longitudinal wall section extending forward from said housing, said wall section substantially surrounding said opening.

17. The device of claim 16 wherein said wall section comprises at least one aperture for providing access to said opening.

18. The device of claim 16 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard including a recess for receiving said protrusion.

19. The device of claim 18 wherein said triggering means comprises a finger pad positioned on said latching arm for manually disengaging said latching arm from said needle guard.

20. The device of claim 18 wherein said triggering means comprises a ramp positioned on said latching arm for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

21. The device of claim 8 further comprising a needle guard hub coupled to said housing, said hub having a longitudinal wall section extending forward from said hub, said resilient member disposed between said hub and said needle guard.

22. The device of claim 21 wherein said wall section comprises an aperture for accessing said needle.

23. The device of claim 21 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said wall section of said hub, said distal end of said latching arm comprising a protrusion, said needle guard having a recess for receiving said protrusion..

24. The device of claim 23 wherein said triggering means comprises a finger pad on said latching arm for manually disengaging said latching arm from said needle guard.

25. The device of claim 23 wherein said triggering means comprises a ramp for biasing said latching arm in an outward manner when a rearward force is applied to said needle guard.

26. The assembly of claim 7 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

27. The assembly of claim 26 wherein said needle trap comprises a lead-in section having a second notch, said lead-in section locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

28. The assembly of claim 26 wherein said needle trap comprises a lead-in section having a multilevel landing, said lead-in section locating said resilient member within said first notch and said landing, said landing releasably retaining said distal end of said resilient member.

29. The assembly of claim 7 wherein said needle trap comprises at least one longitudinal channel for reducing the contact surface area between said needle trap and said resilient member.

30. The assembly of claim 8 wherein said limiting means comprises a tether having a first end and a second end, said first end

attached to said housing, said second end attached to said needle guard.

31. The assembly of claim 21 wherein said limiting means comprises a tether having a first end and a second end, said first end attached to said hub, said second end attached to said needle guard.

32. The assembly of claim 30 or 31 wherein said tether is flexible.

33. The assembly of claim 8 wherein said limiting means comprises a rigid tether and said housing includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said housing aperture, said second end attached to said needle guard.

34. The assembly of claim 21 wherein said limiting means comprises a rigid tether and said hub includes an aperture for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said hub aperture, said second end attached to said needle guard.

35. The assembly of claim 32 wherein said hub includes a pocket for storing said flexible tether.

36. The assembly of claim 1 wherein said needle includes a change in contour near the sharpened distal end of said needle, said change in contour providing the limiting means to limit the forward movement of said needle guard along said needle.

37. The assembly of claim 8 wherein said housing comprises at least one projection for removably attaching a protective storage cover to said housing.

38. The assembly of claim 21 wherein said hub comprises at least one projection for removably attaching a protective storage cover to said hub.

39. The assembly of claim 1 wherein said needle guard is side-loadable onto said needle.

40. The assembly of claim 1 wherein said needle guard comprises a first section and a second section, said first and second sections having attachable mating faces.

41. The assembly of claim 40 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

42. The assembly of claim 39 wherein said needle guard includes a longitudinal recess for receiving said needle.

43. The assembly of claim 7 further comprising a shroud for containing said resilient member and said needle guard.

44. The assembly of claim 46 wherein said shroud comprises a collapsible bellows.

45. The assembly of claim 7 further comprising a shroud for containing said needle guard and said needle when the sharpened distal end of said needle is contained within said needle guard, said shroud comprising a bellows, said bellows providing the limiting means to limit the forward movement of said needle guard along said needle.

46. An intravenous catheter assembly comprising:

a catheter hub comprising a proximal end and a distal end;

a needle having a proximal end and a sharpened distal end;

a needle guard slidably mounted on said needle, said needle guard having a proximal end and a distal end, said needle guard containing a movable needle trap that is urged toward said needle, said needle trap entrapping said sharpened distal end of said needle when said distal end of said needle guard moves forward of said sharpened distal end of said needle, said needle guard releasably coupled to said proximal end of said catheter hub;

limiting means for limiting the axial movement of said needle guard; and

a hub comprising a needle nest for receiving the proximal end of said needle.

47. The assembly of claim 46 wherein said needle trap is integral to said needle guard.

48. The assembly of claim 46 wherein said needle trap is inherently urged toward said needle.

49. The assembly of claim 46 wherein said distal end of said needle trap comprises a needle tip guard for entrapping said sharpened distal end of said needle.

50. The assembly of claim 46 further comprising a resilient member for urging said needle trap toward said needle.

51. The assembly of claim 50 wherein said resilient member comprises a proximal end and a distal end.

52. The assembly of claim 51 wherein said resilient member comprises a coil spring.

53. The assembly of claim 51 wherein said distal end of said resilient member is retained at the proximal end of said needle guard.

54. The assembly of claim 46 further comprising a collar that is attached to the proximal end of said needle guard.

55. The assembly of claim 54 further comprising a resilient member having a proximal end and a distal end, said proximal end of said resilient member being retained on said collar.

56. The assembly of claim 51 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

57. The assembly of claim 56 wherein said needle trap comprises a lead-in section having a second notch, said lead-in section locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

58. The assembly of claim 50 wherein said needle trap comprises at least one longitudinal channel for reducing the contact surface area between said needle trap and said resilient member.

59. The assembly of claim 49 wherein said needle tip guard comprises at least one skirt.

60. The assembly of claim 46 wherein said needle guard includes a finger post for advancing said needle guard along said needle.

61. The assembly of claim 46 wherein said proximal end of said catheter hub includes a recess.

62. The assembly of claim 61 wherein said needle guard is releasably coupled to said catheter by a male section comprising an arm having a proximal end and a distal end, said proximal end of said arm attached to said needle trap, said distal end of said arm having a projection, said projection being received within said recess of said catheter hub to couple said needle guard with said catheter hub.

63. The assembly of claim 46 wherein said proximal end of said catheter hub includes a projection.

64. The assembly of claim 63 wherein said needle guard is releasably coupled to said catheter by a male section comprising an arm having a proximal end and a distal end, said proximal end of said arm attached to said needle trap, said distal end of said arm having a recess, said projection of said catheter hub being received within said recess of said arm to couple said needle guard with said catheter hub.

65. The assembly of claim 46 wherein said needle guard includes at least one internal guide section to maintain said needle and said needle guard in sliding alignment.

66. The assembly of claim 46 wherein said limiting means comprises a tether having a first end and a second end, said first end attached to said hub, said second end attached to said needle guard.

67. The assembly of claim 62 wherein said tether is flexible.

68. The assembly of claim 46 wherein said limiting means comprises a rigid tether and said hub includes an aperture and for receiving said rigid tether, said rigid tether having a first end and a second end, said first end having a stop to prevent said first end of said rigid tether from advancing through said hub aperture, said second end attached to said needle guard.

69. The assembly of claim 46 wherein said needle guard is side-loadable onto said needle.

70. The assembly of claim 52 wherein said collar is side-loadable onto said needle.

71. The assembly of claim 67 wherein said hub includes a pocket for storing said flexible tether.

72. The assembly of claim 50 wherein said needle trap comprises a lead-in section that is followed by a multilevel landing, said lead-in area locating said spring within first notch an said landing, said landing releasably retaining said distal end of said resilient member.

73. The assembly of claim 46 wherein said needle includes a change in contour near the sharpened distal end of said needle, said

change in contour providing the limiting means to limit the axial movement of said needle guard along said needle.

74. The assembly of claim 46 wherein said hub comprises at least one projection for removably attaching a protective storage cover to said hub.

75. The assembly of claim 46 wherein said hub includes a flashback chamber, said needle in fluid communication with said flashback chamber.

76. The assembly of claim 46 wherein said hub comprises a proximal end and a distal end, said hub including a longitudinal wall section at said distal end of said hub, said wall section substantially surrounding said needle nest.

77. The assembly of claim 76 wherein said wall section comprises at least one aperture for providing access to said needle nest.

78. The assembly of claim 46 wherein said needle guard comprises a first section and a second section, said first and second sections having attachable mating faces.

79. The assembly of claim 46 wherein said needle guard comprises an integral configuration whereby said first and second sections are joined by a hinge section.

80. The assembly of claim 46 wherein said needle guard includes a longitudinal recess for receiving said needle.

81. The assembly of claim 46 further comprising a resilient member that is disposed between said hub and said needle guard, said resilient member urging said needle guard toward said sharpened distal end of said needle.

82. The assembly of claim 81 wherein said resilient member comprises a proximal end and a distal end.

83. The assembly of claim 82 wherein said resilient member comprises a coil spring.

84. The assembly of claim 81 wherein said needle guard comprises a first notch for retaining said distal end of said resilient member.

85. The assembly of claim 84 wherein said needle trap comprises a lead-in section having a second notch, said lead-in area locating said resilient member within first and second notches, said second notch releasably retaining said distal end of said resilient member.

86. The assembly of claim 81 further comprising retaining means for releasably retaining said needle guard adjacent to said hub.

87. The assembly of claim 86 wherein said retaining means comprises a latching arm having a proximal end and a distal end, said proximal end of said latching arm hingedly attached to said hub, said distal end of said latching arm having a protrusion.

88. The assembly of claim 87 wherein said needle guard includes a recess for receiving said latching arm protrusion.

89. The assembly of claim 87 wherein said latching arm further comprises a finger pad for manually disengaging said latching arm from said needle guard.

90. The assembly of claim 87 wherein said latching arm further comprises a ramp for biasing the latching arm in an outward manner when a compressive force is applied to said needle guard.

91. The assembly of claim 46 further comprising a housing for containing said resilient member and said needle guard.

92. The assembly of claim 91 wherein said housing comprises a collapsible bellows.

93. The assembly of claim 92 wherein said bellows provides the limiting means to limit the axial movement of said needle guard along said needle.

ABSTRACT OF THE INVENTION

A needle tip protective device. In one embodiment the needle tip protective device includes a needle guard that is slidably mounted on a hypodermic needle having a needle tip located at the distal end of the needle. The needle guard contains a movable needle trap that is biased against or toward the hypodermic needle. The needle trap advances over the tip of the needle, entrapping the needle tip as the needle guard is urged forward near the sharpened distal end of the hypodermic needle. A tether, or other limiting means, limits the forward movement of the needle guard along the needle. In one embodiment, the needle guard is manually urged forward along the shaft of the needle by the user. In yet another embodiment, a spring, or other biasing means, is used to move the needle guard along the shaft of the needle.

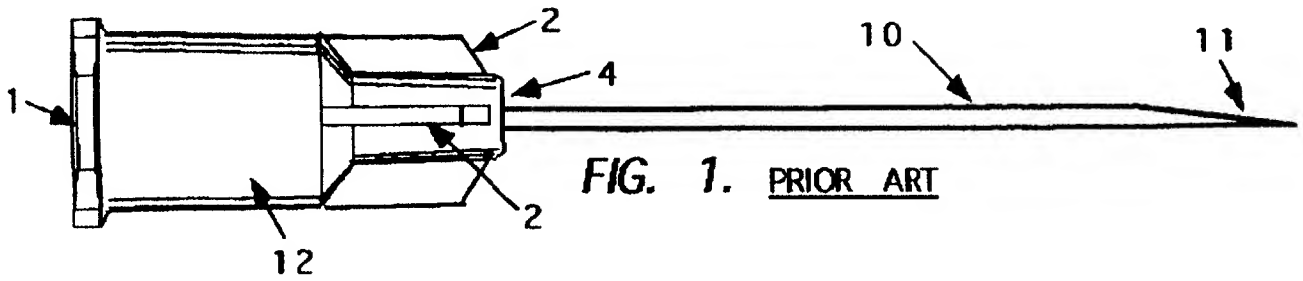

FIG. 1. PRIOR ART

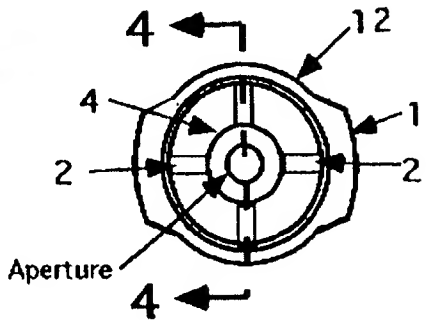

FIG. 2. PRIOR ART

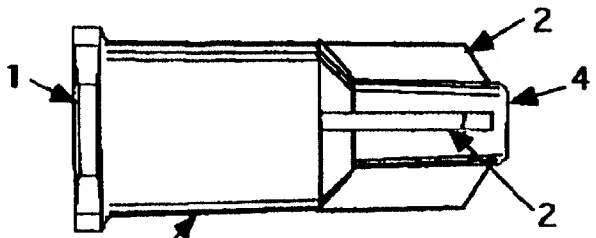

FIG. 3A. PRIOR ART

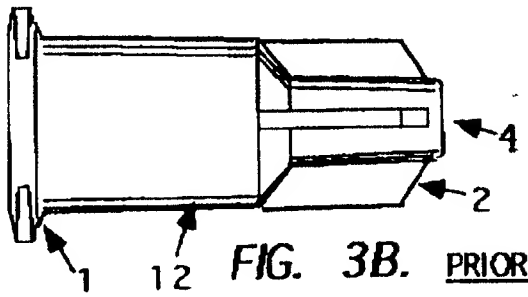

FIG. 3B. PRIOR ART

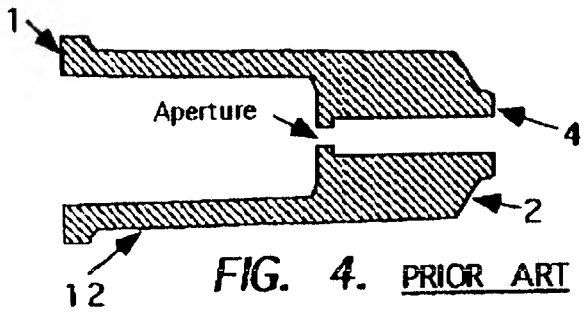

FIG. 4. PRIOR ART

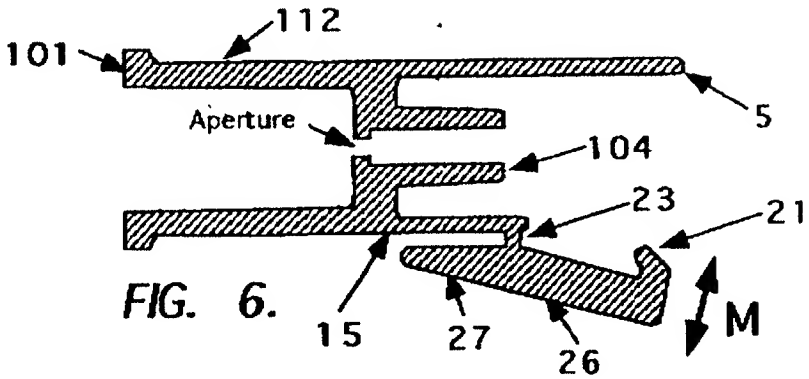

FIG. 6.

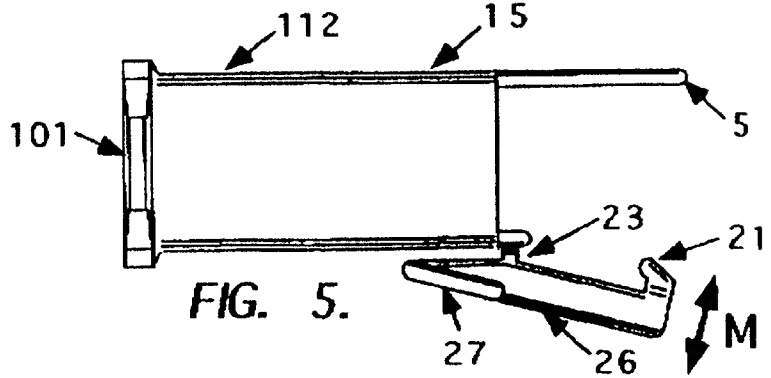

FIG. 5.

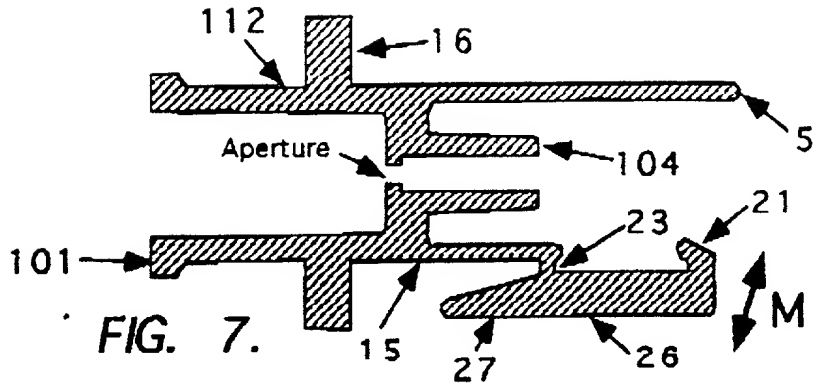

FIG. 7.

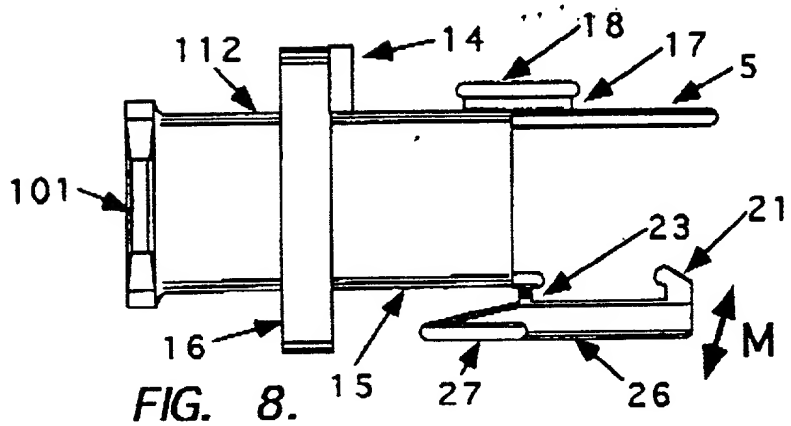

FIG. 8.

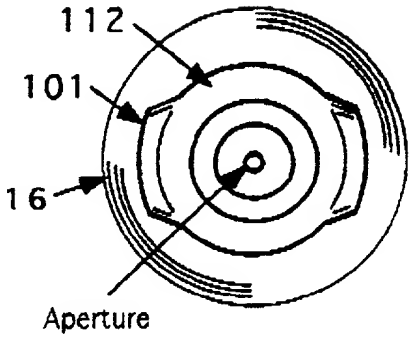

FIG. 9.

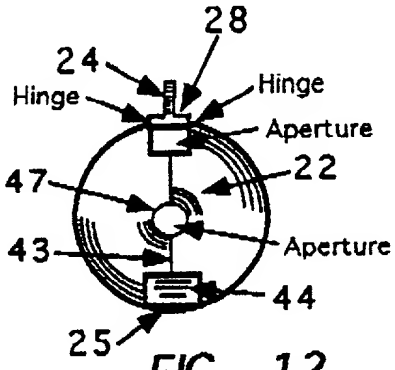

FIG. 12.

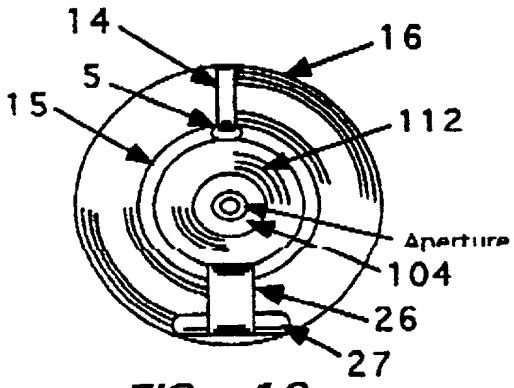

FIG. 10.

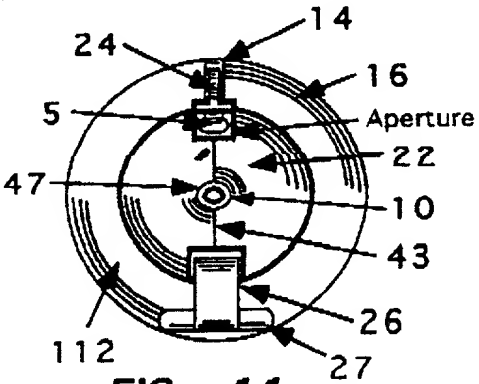

FIG. 11.

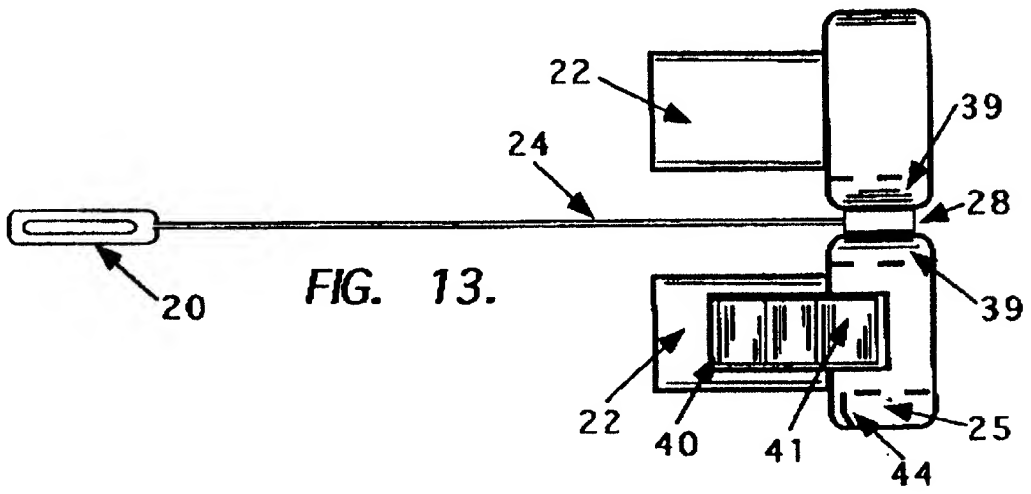

FIG. 13.

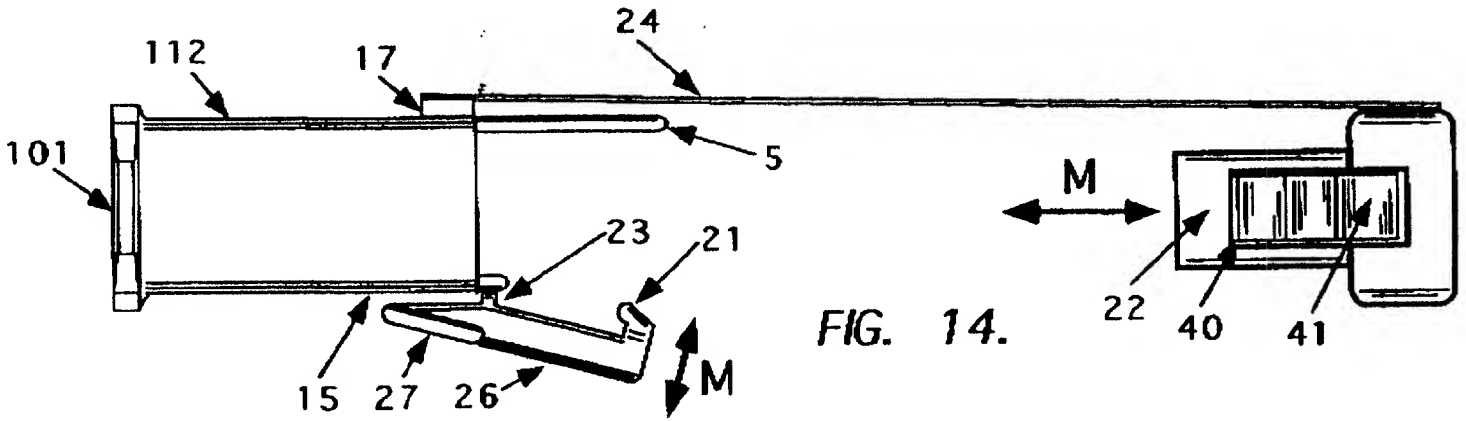

FIG. 14.

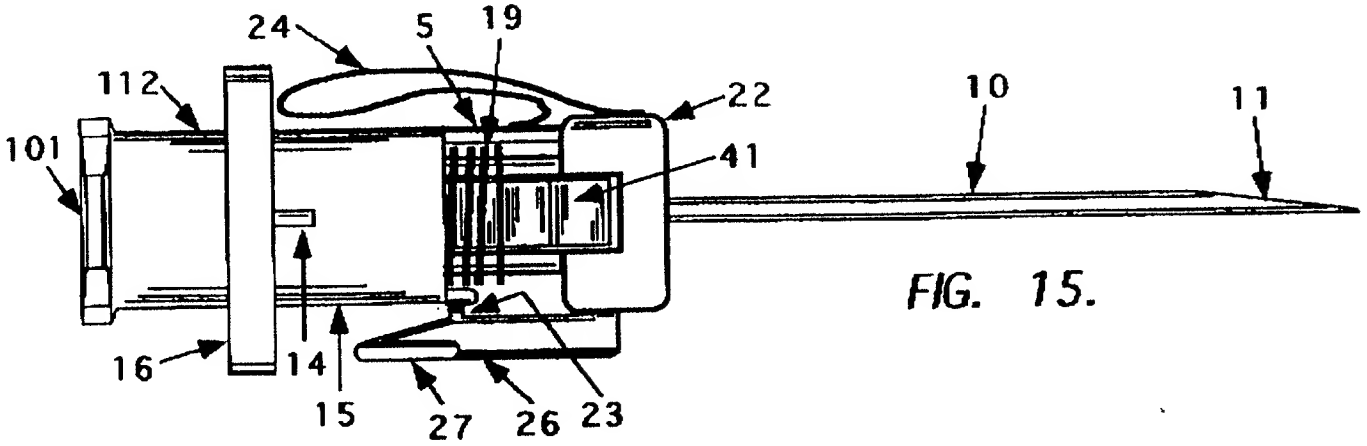

FIG. 15.

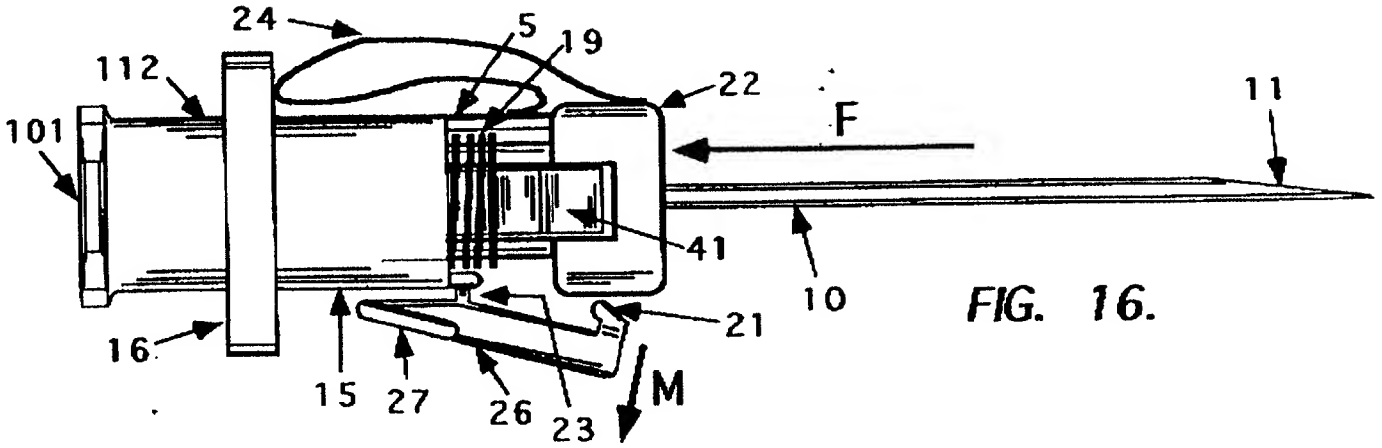

FIG. 16.

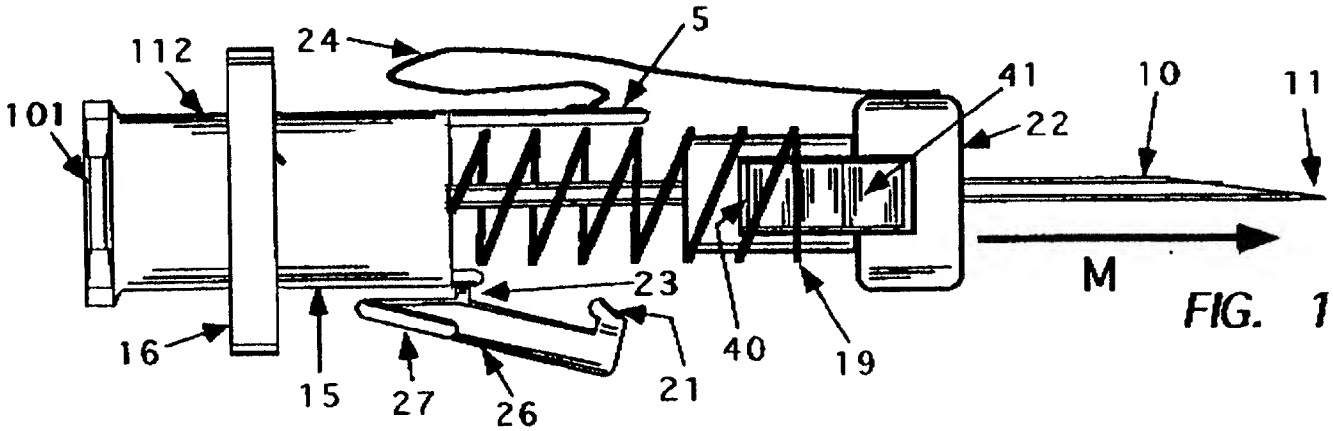

FIG. 17.

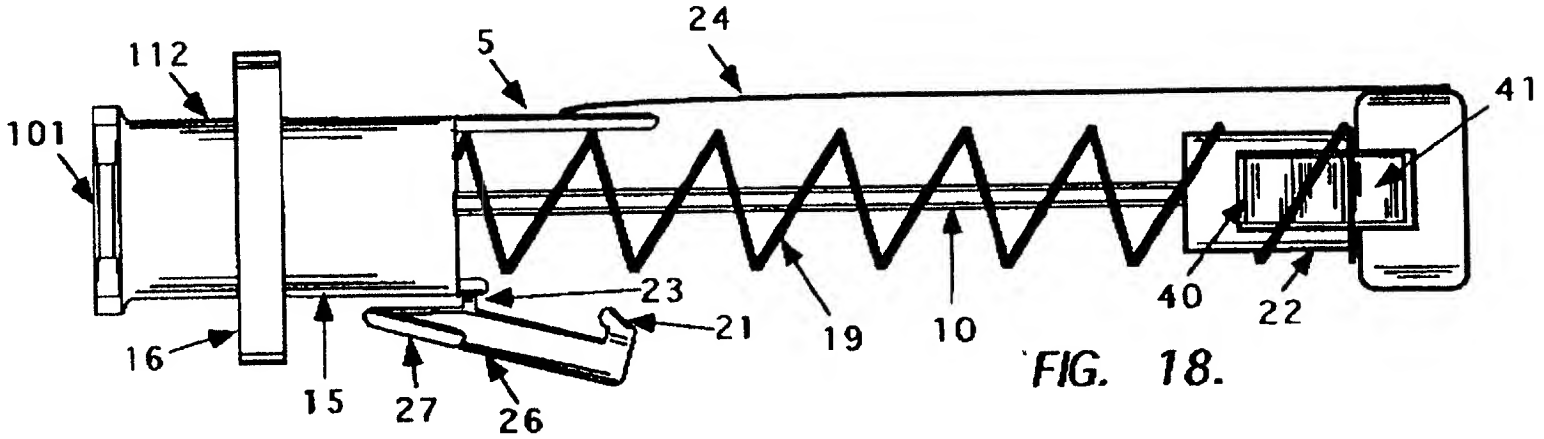

FIG. 18.

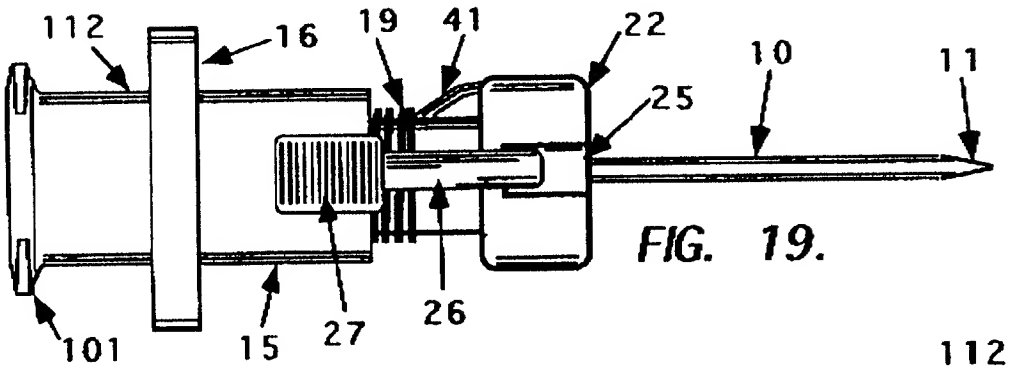

FIG. 19.

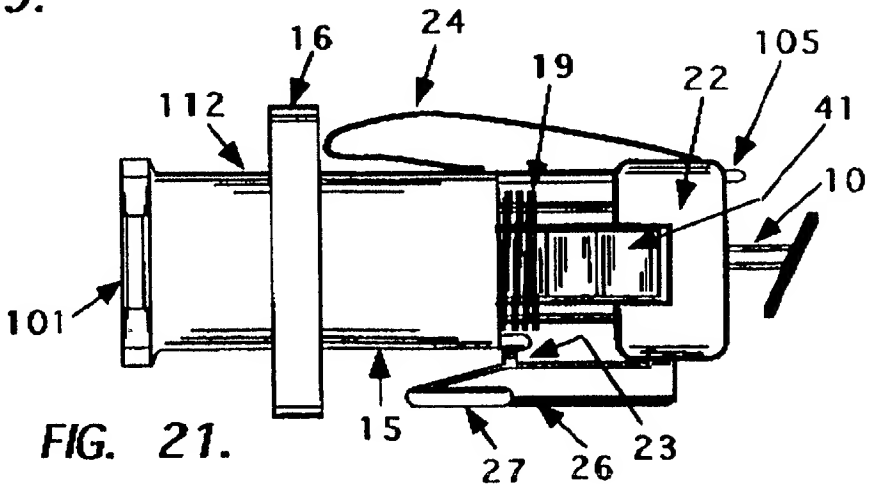

FIG. 21.

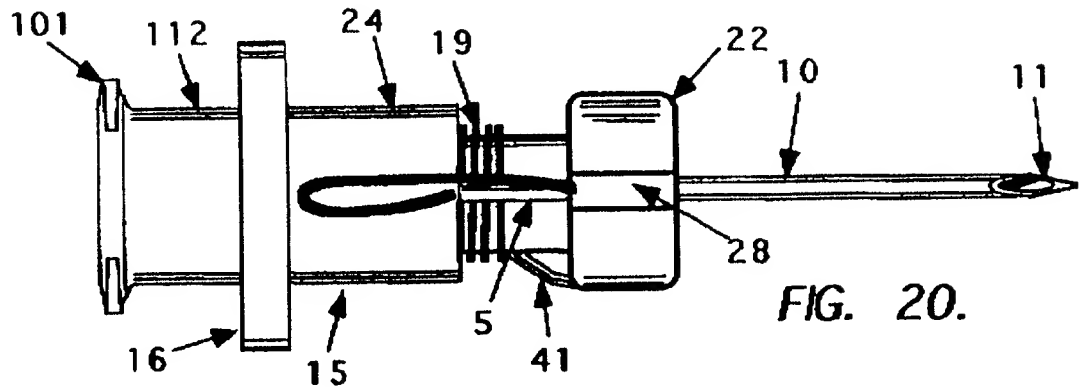

FIG. 20.

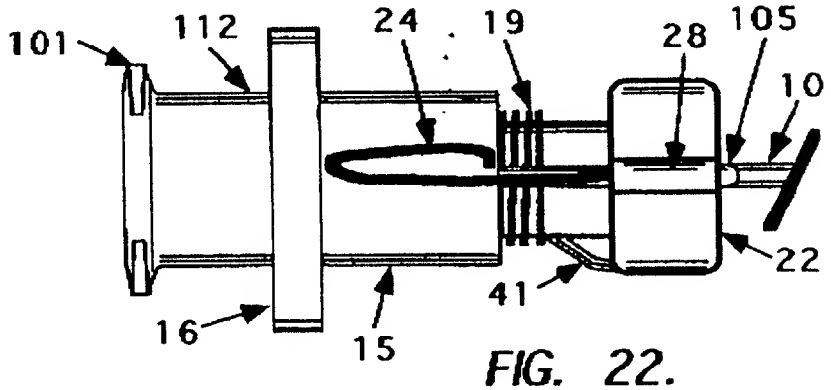

FIG. 22.

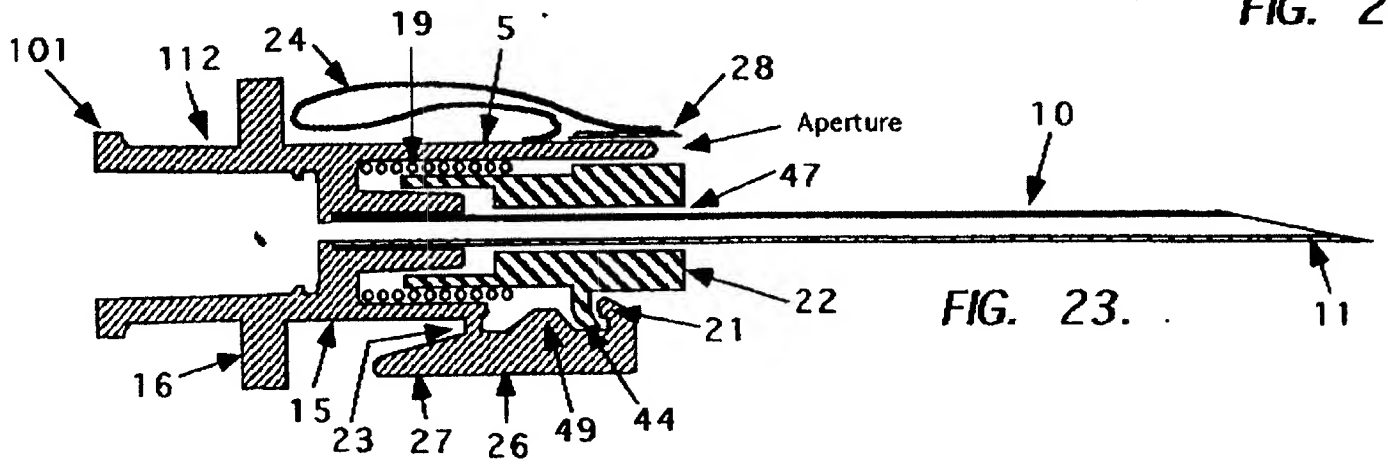

FIG. 23.

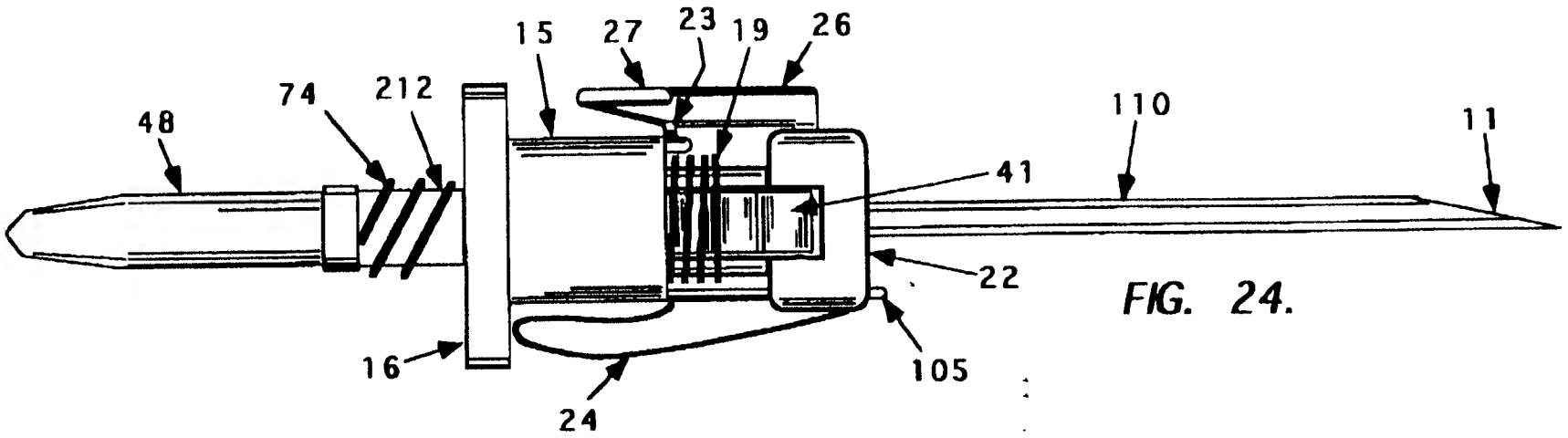

FIG. 24.

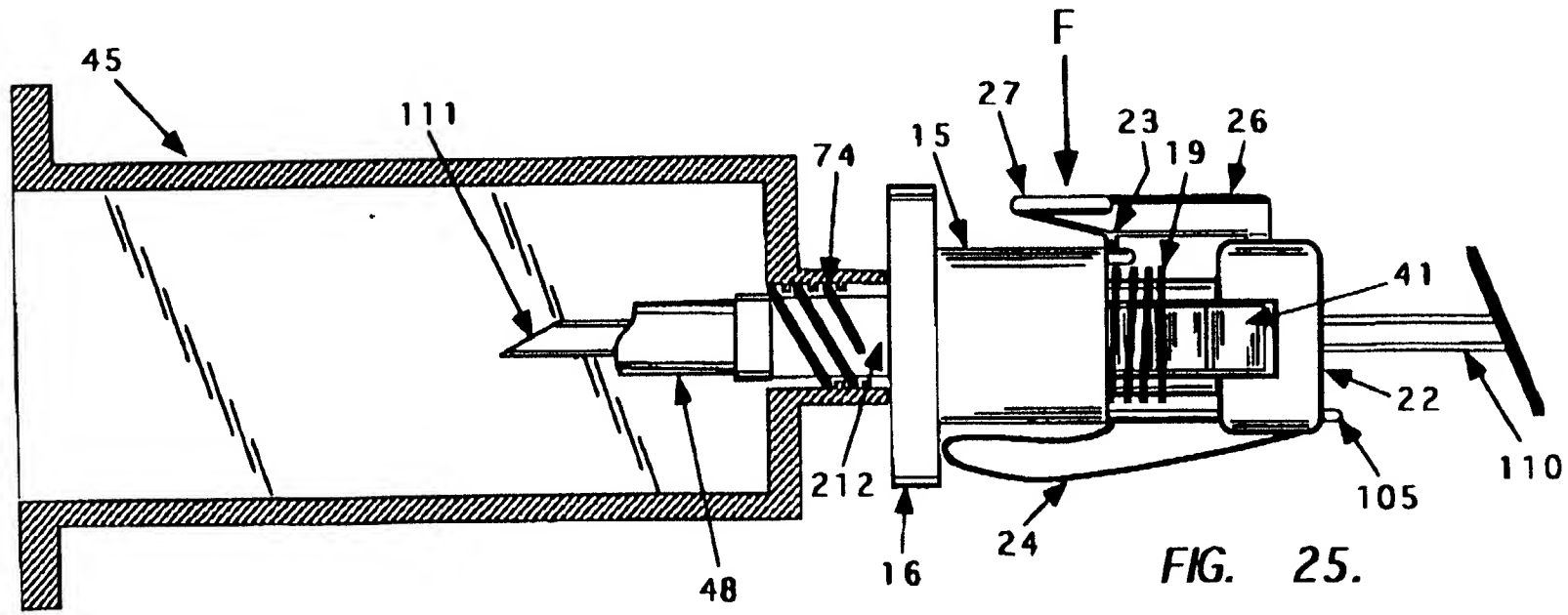

FIG. 25.

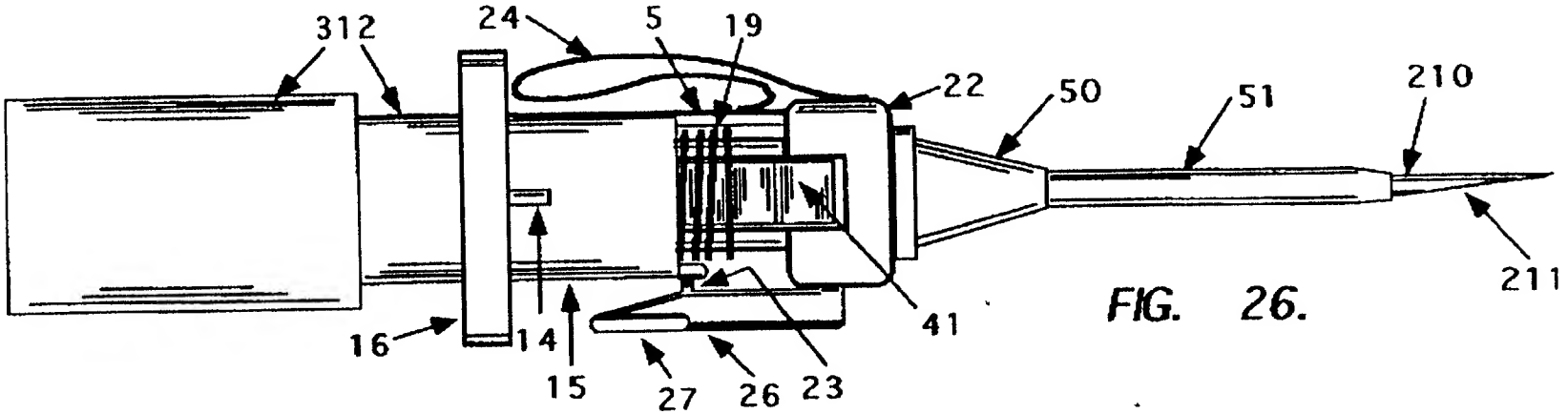

FIG. 26.

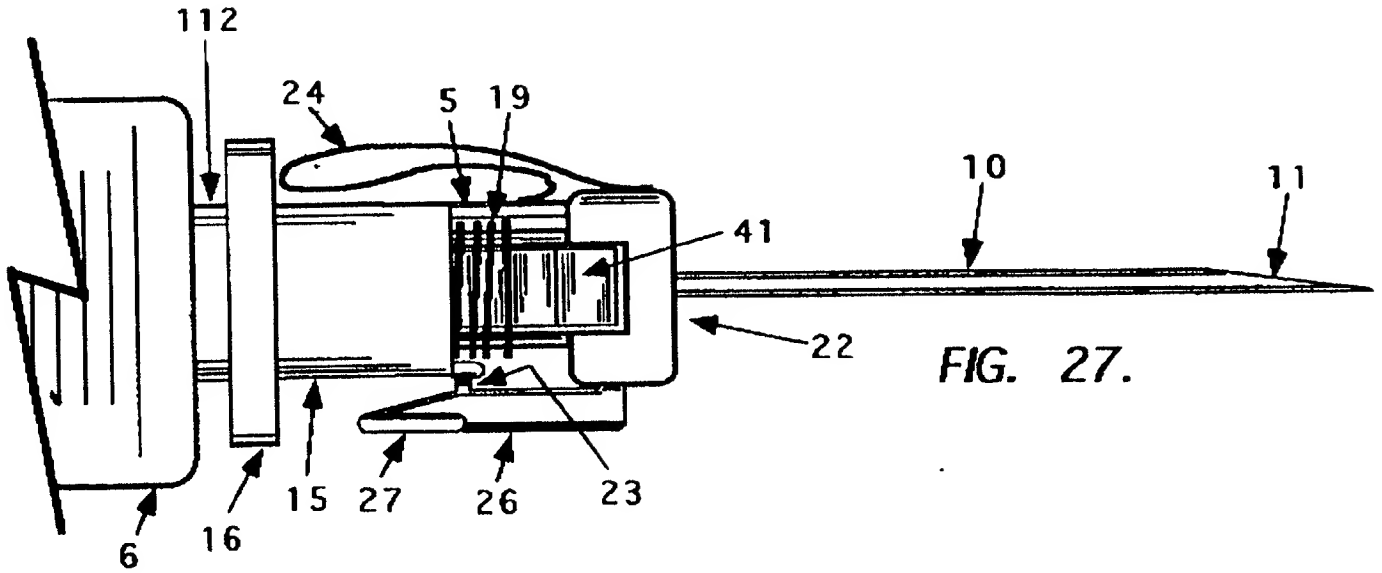

FIG. 27.

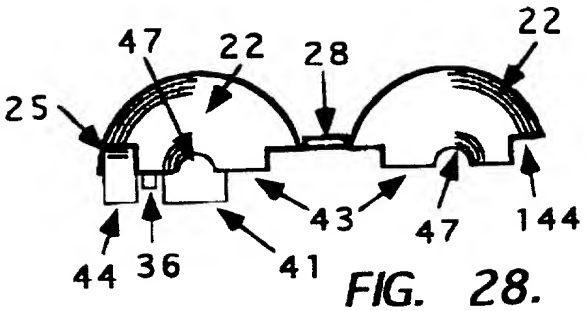

FIG. 28.

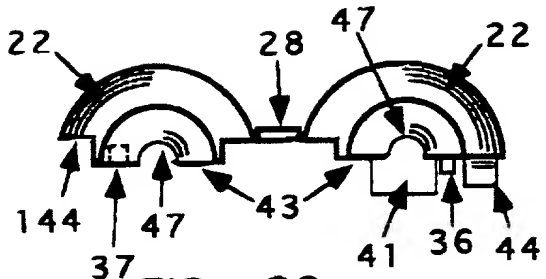

FIG. 29.

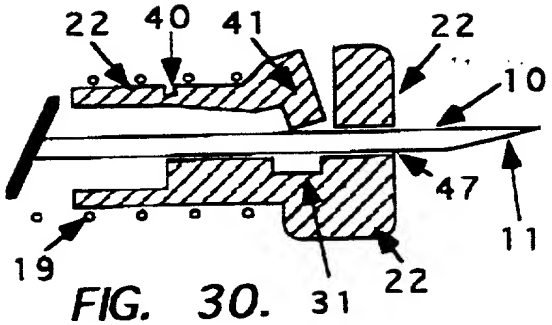

FIG. 30.

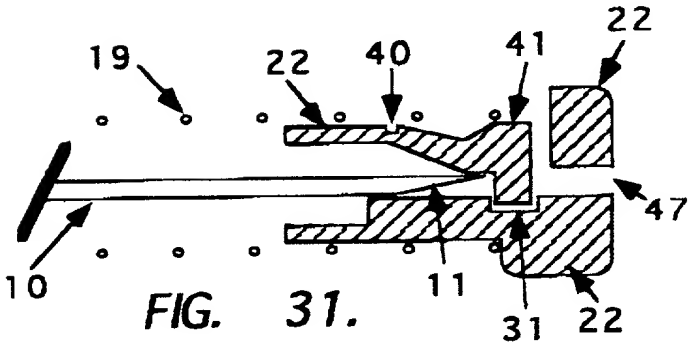

FIG. 31.

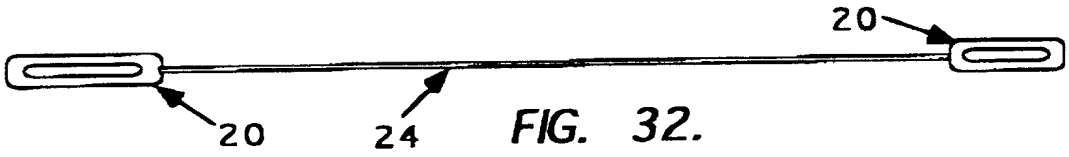

FIG. 32.

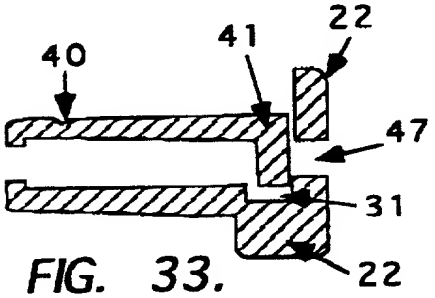

FIG. 33.

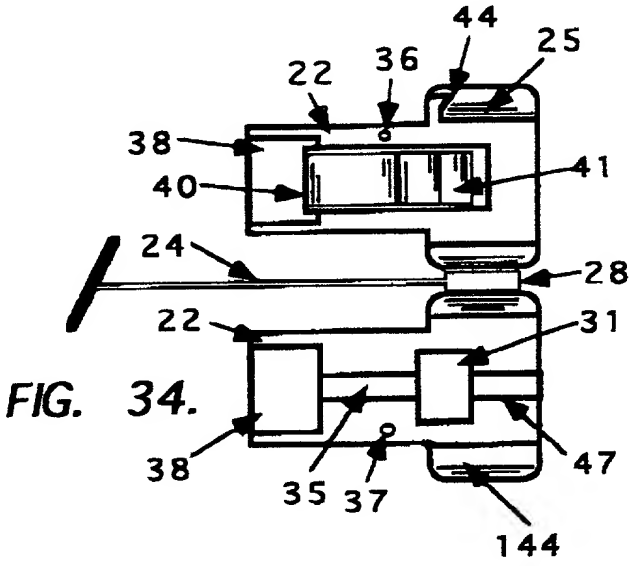

FIG. 34.

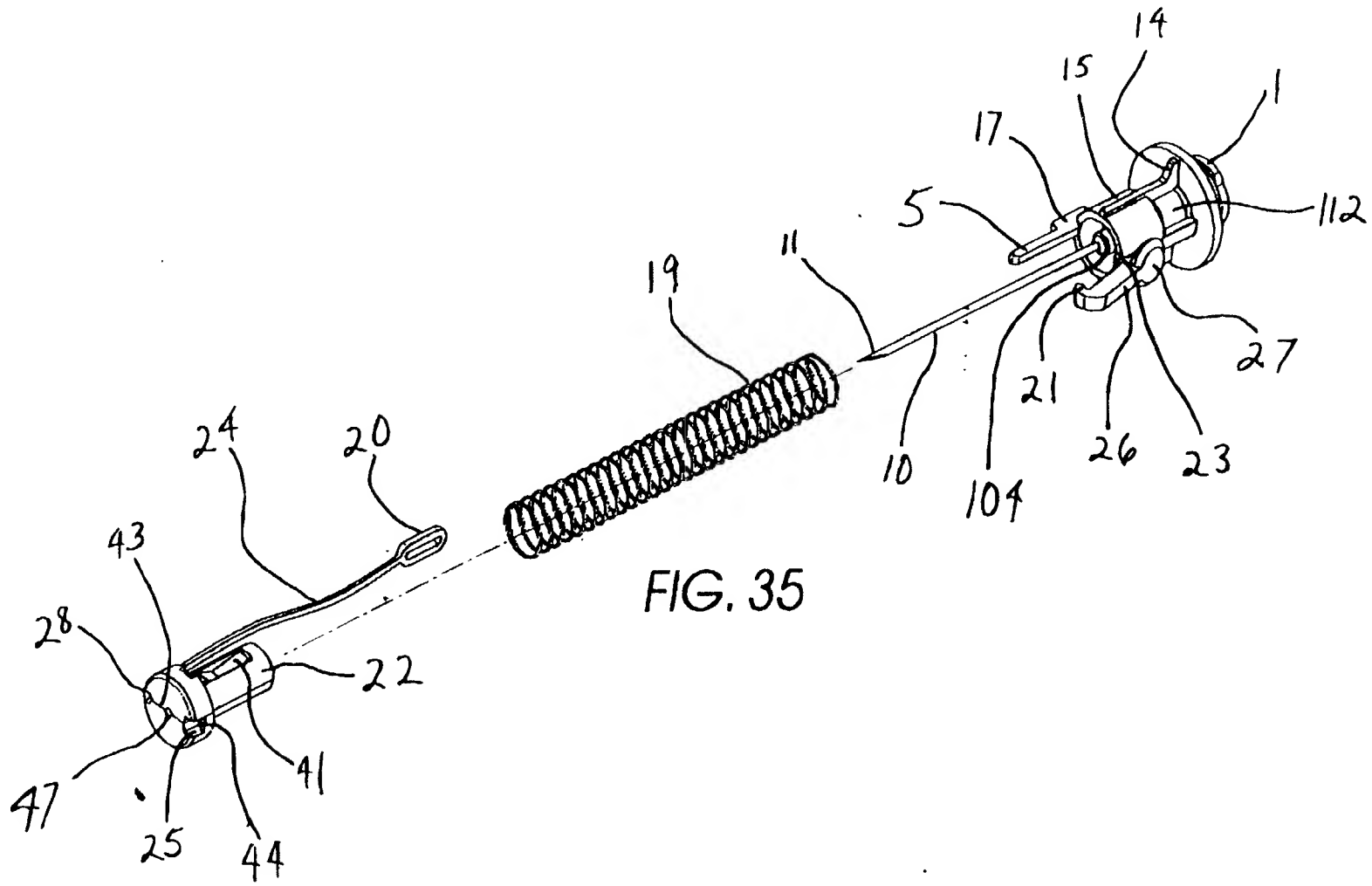

FIG. 35

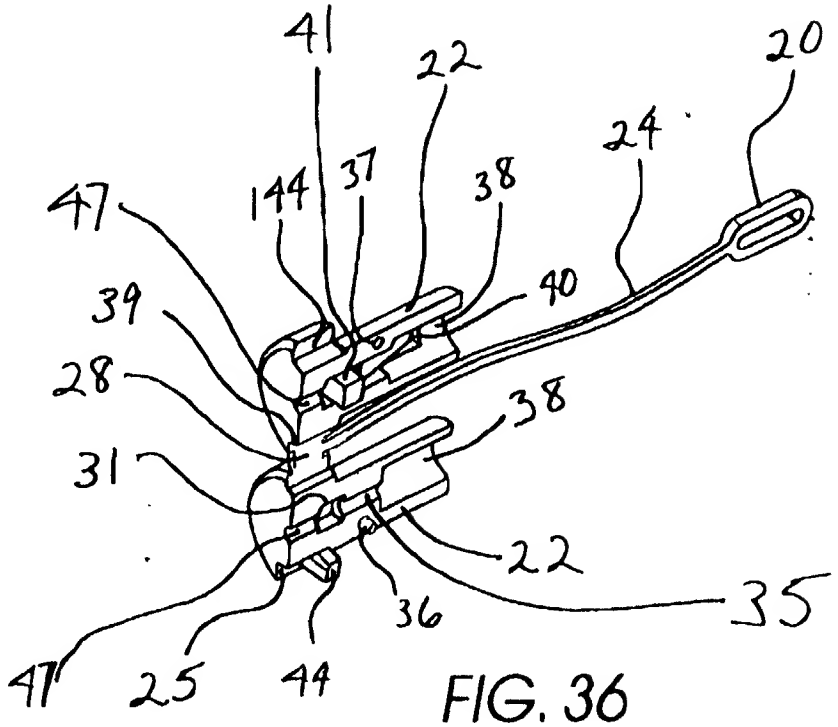

FIG. 36

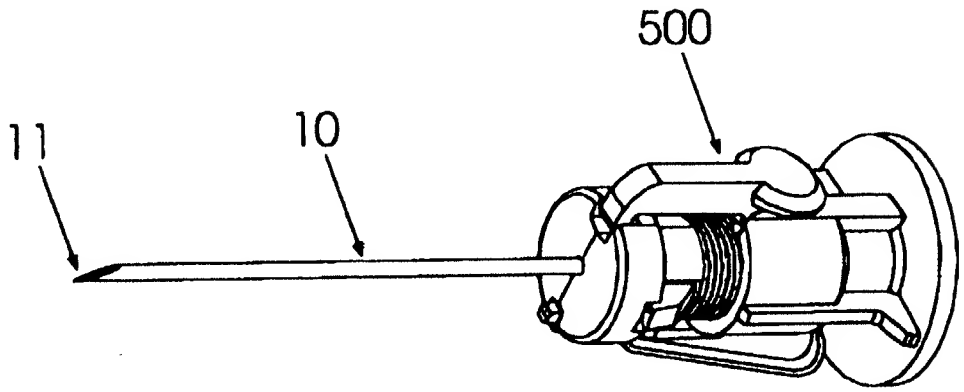

FIG. 37A

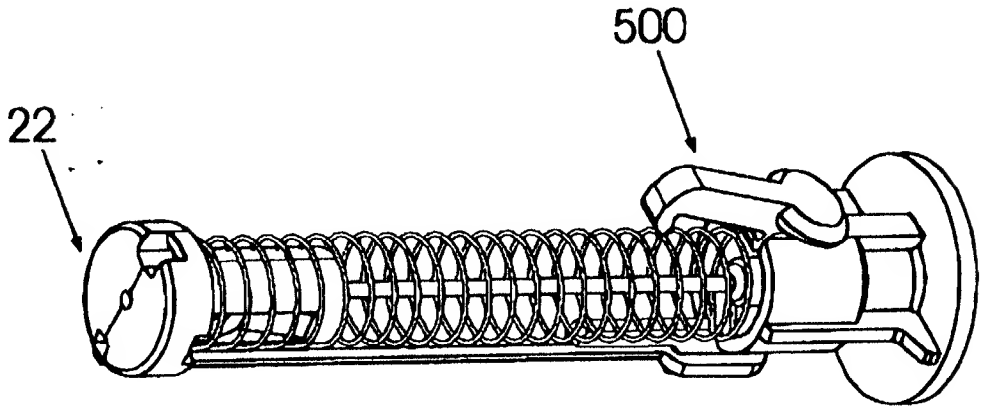

FIG. 37B

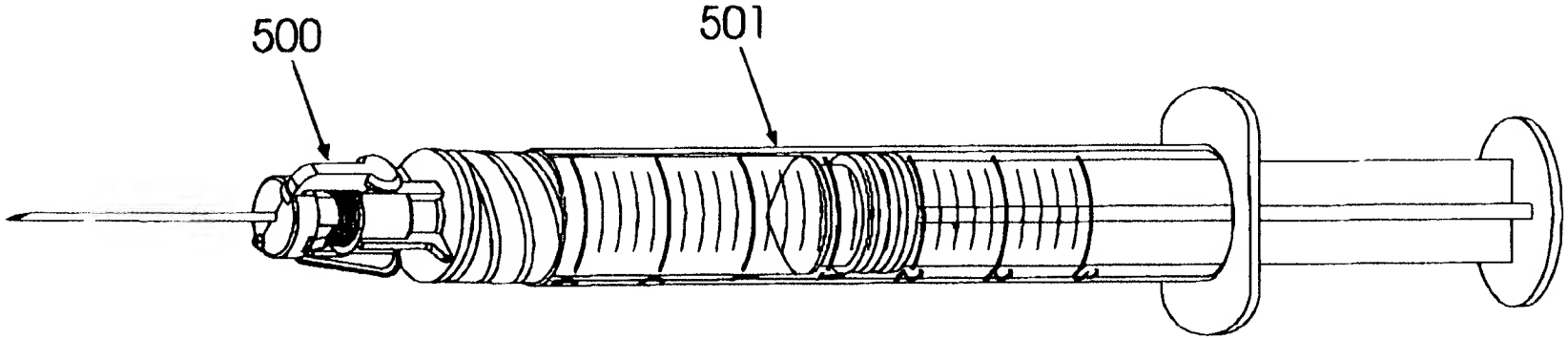

FIG. 38A

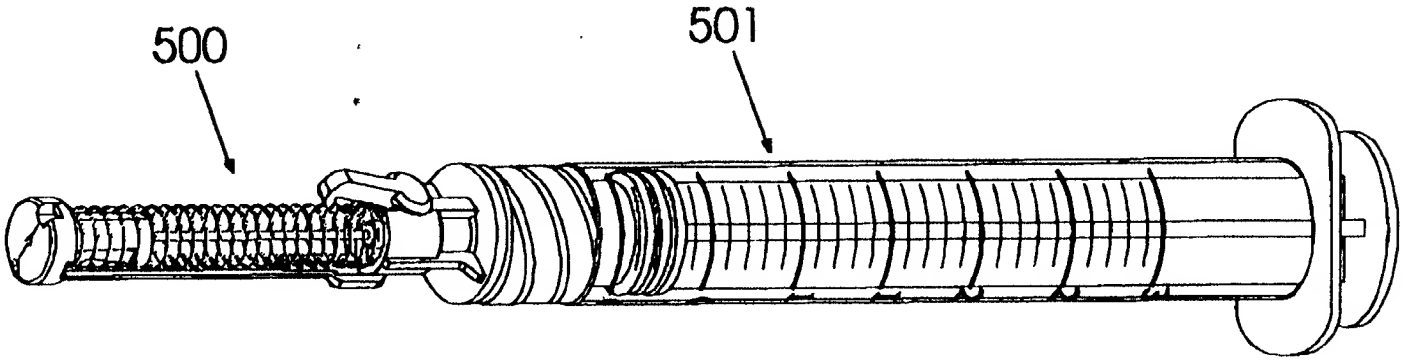

FIG. 38B

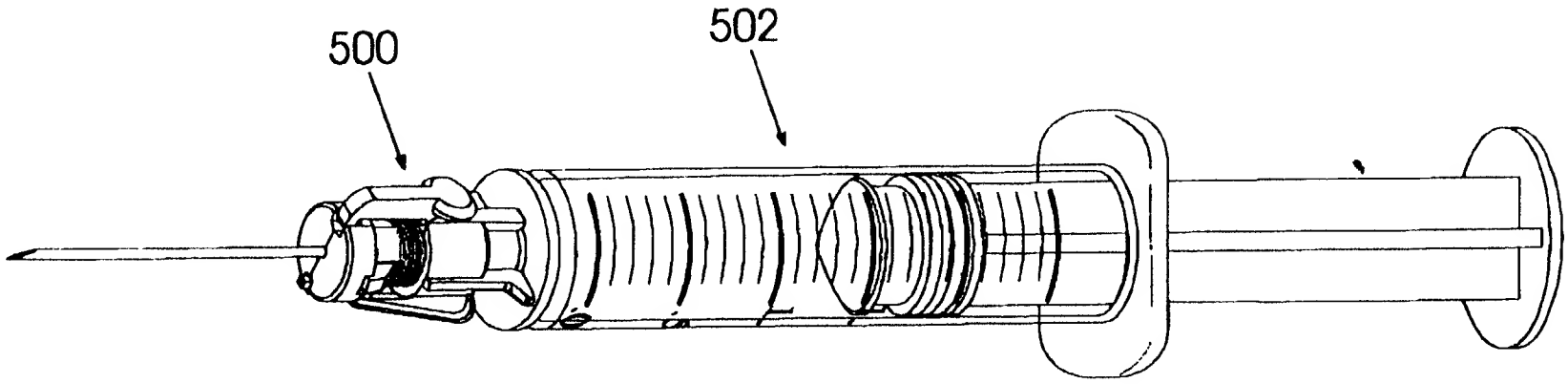

FIG. 39A

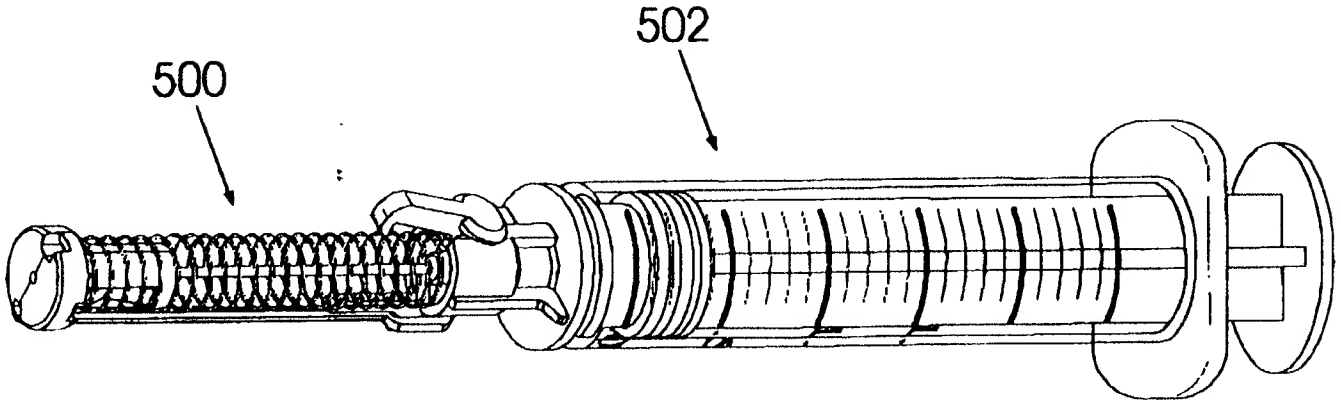

FIG. 39B

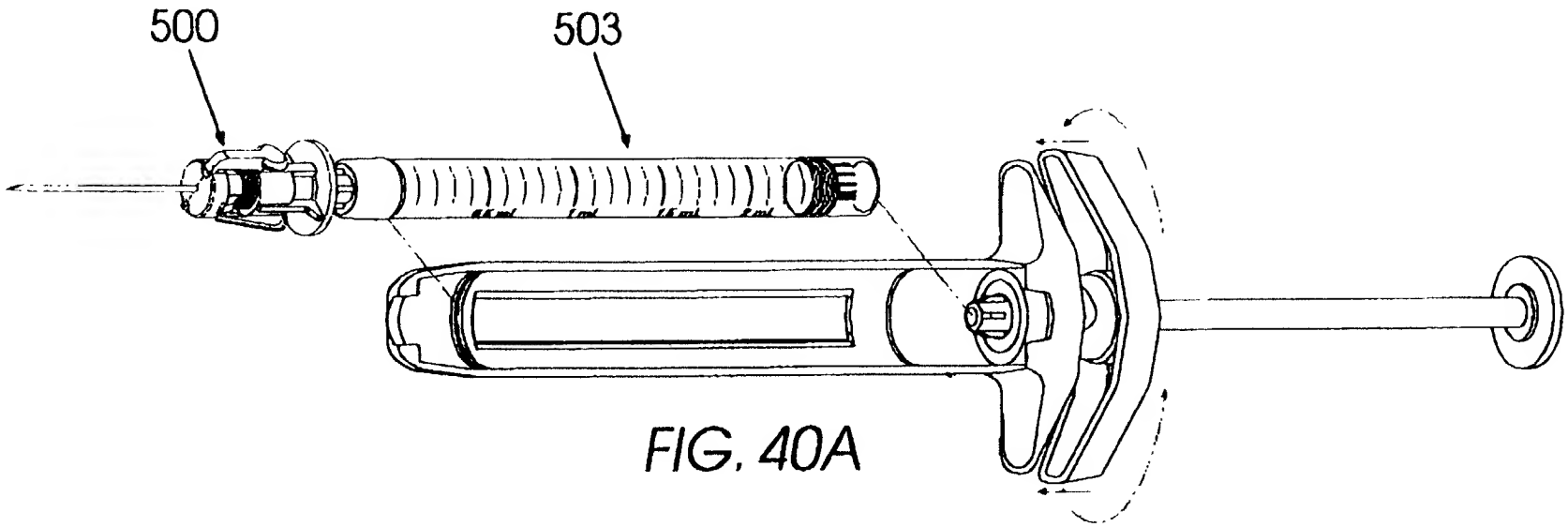

FIG. 40A

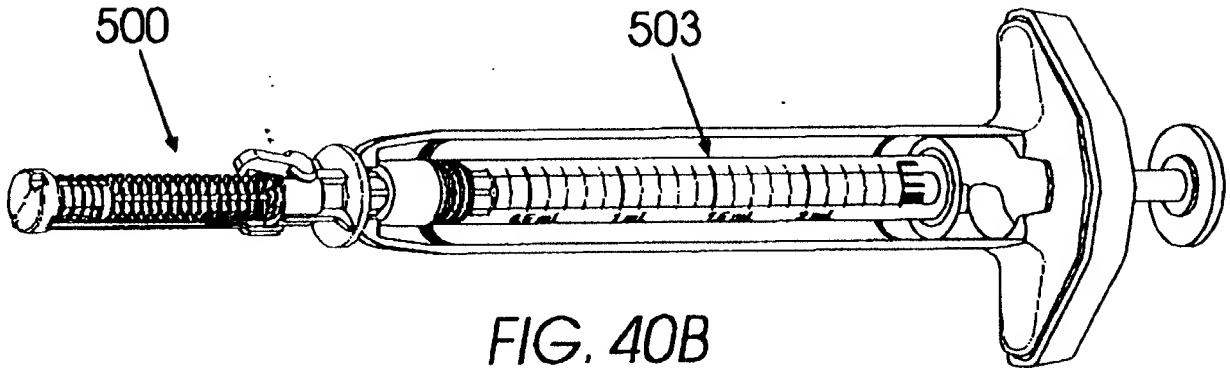

FIG. 40B

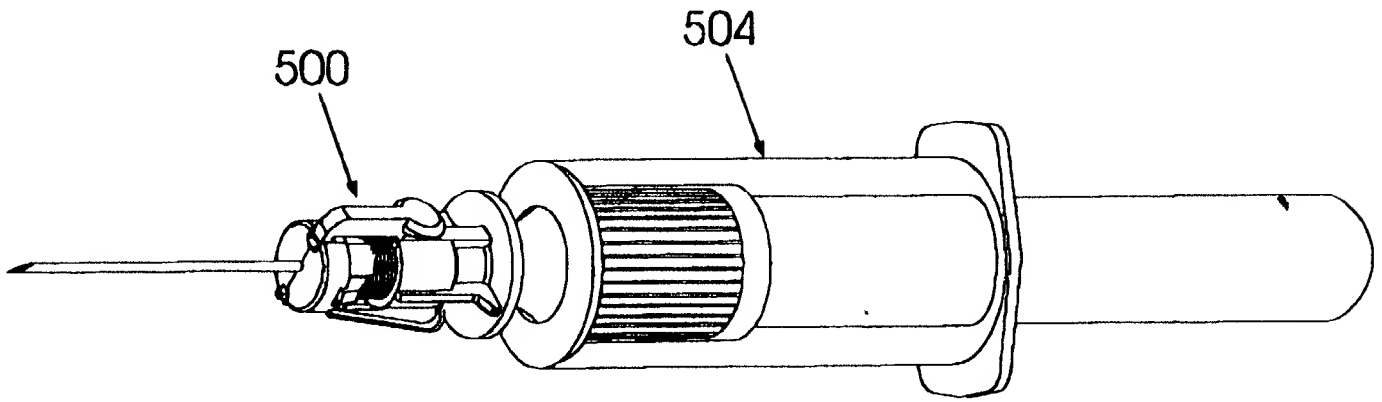

FIG. 41A

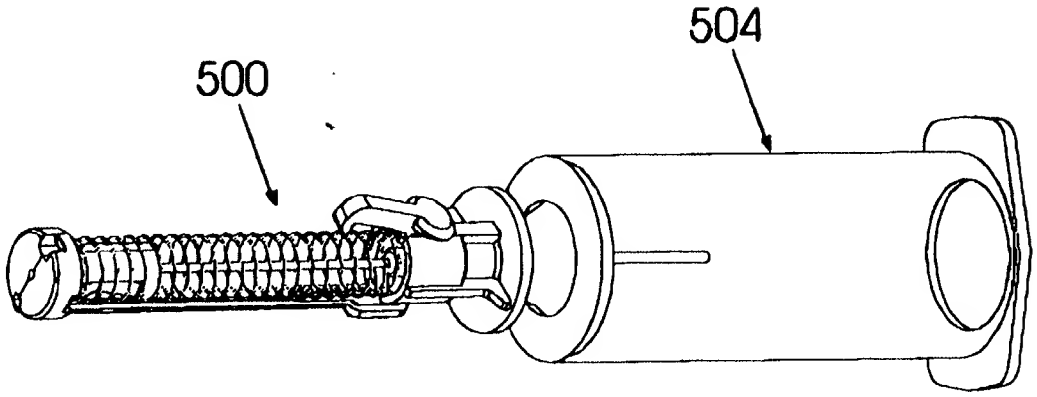

FIG. 41B

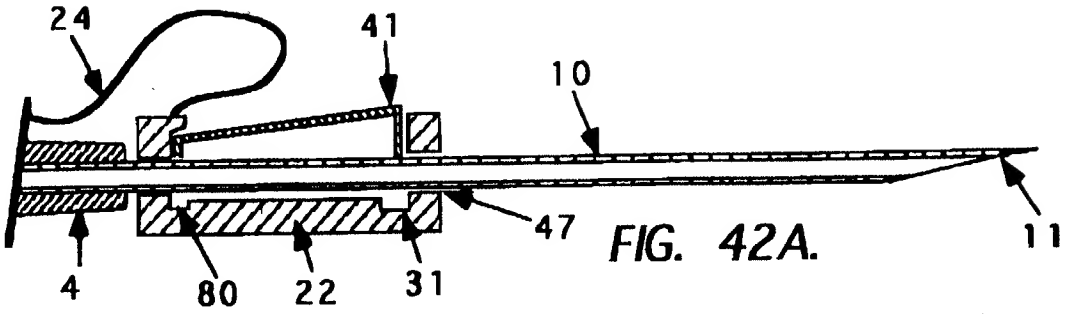

FIG. 42A.

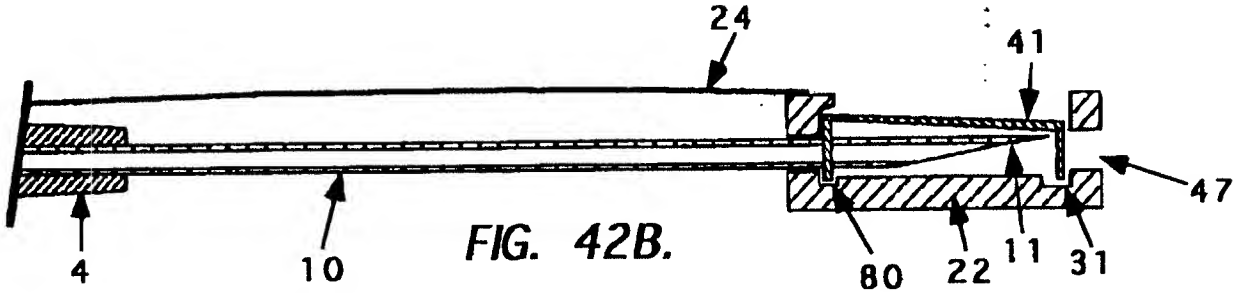

FIG. 42B.

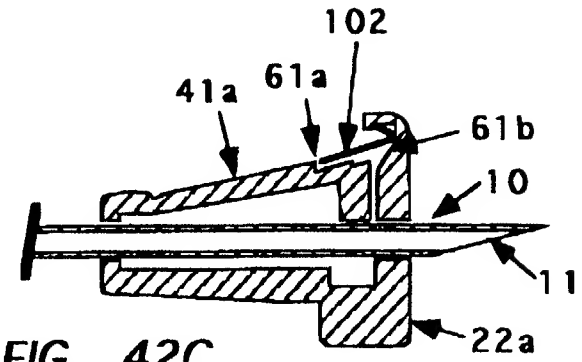

FIG. 42C.

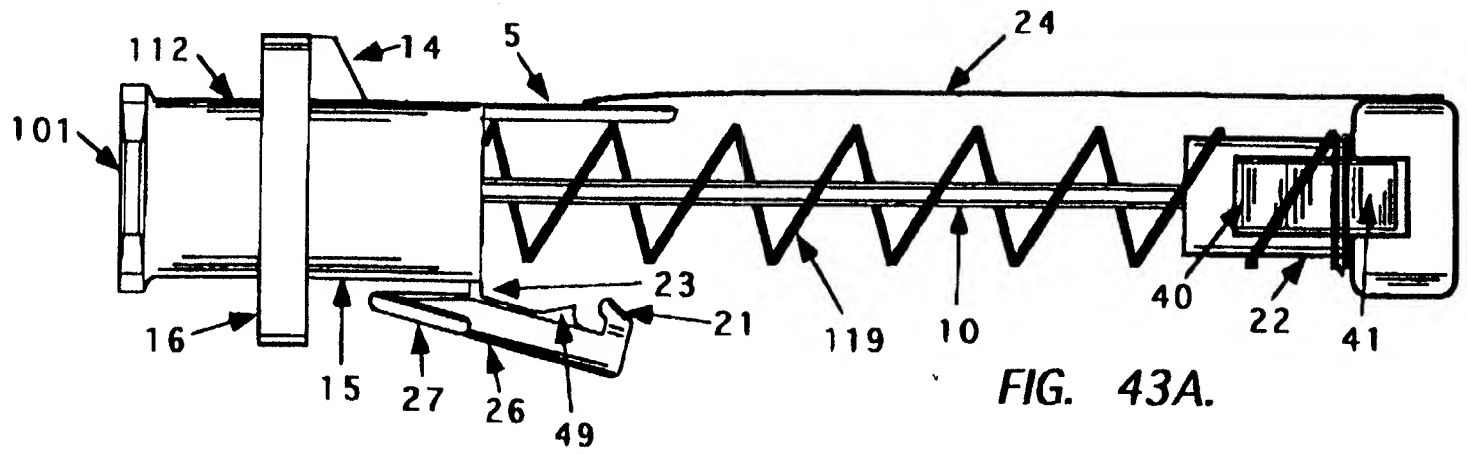

FIG. 43A.

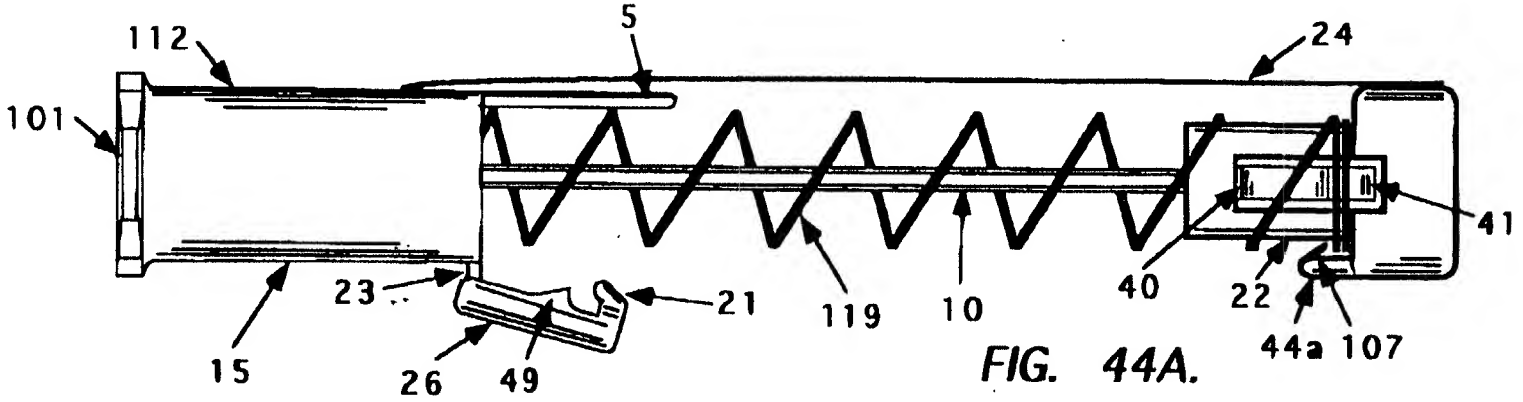

FIG. 44A.

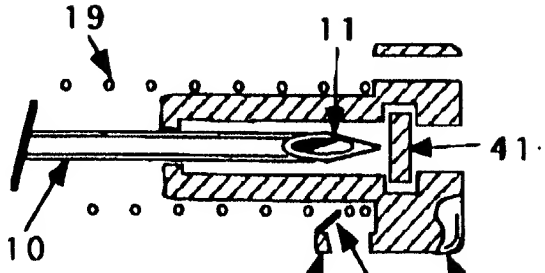

FIG. 44B.

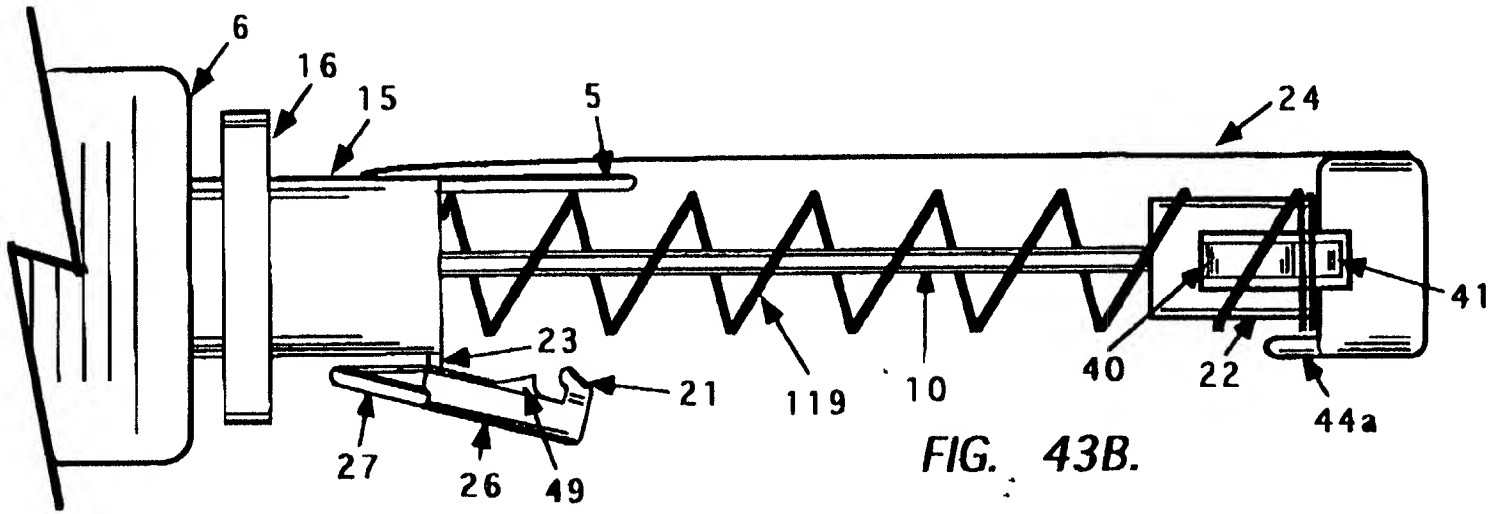

FIG. 43B.

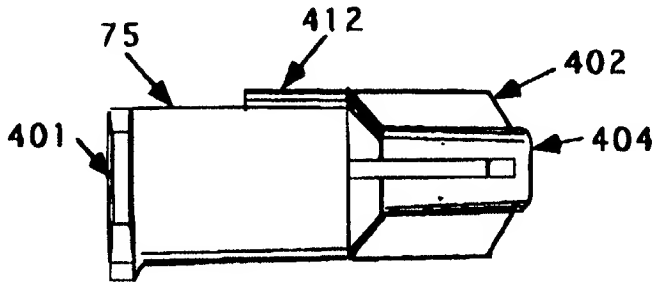

FIG. 45A.

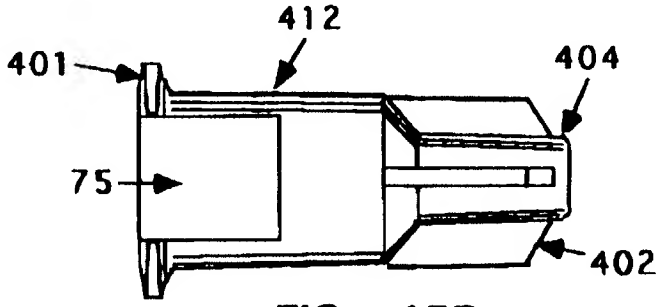

FIG. 45B.

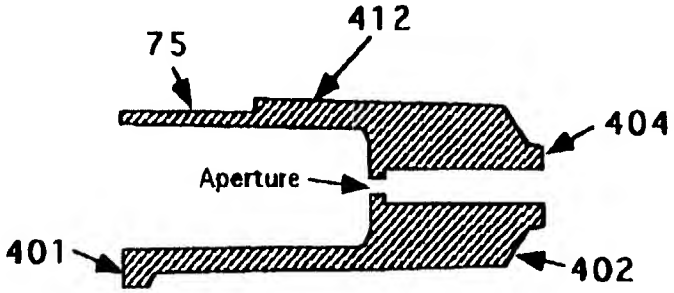

FIG. 45C.

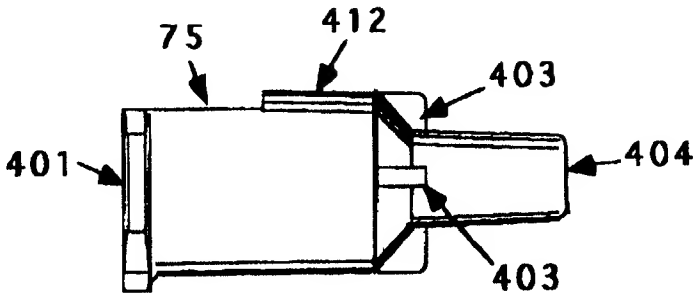

FIG. 46.

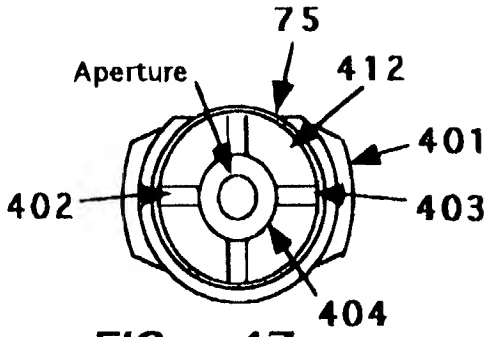

FIG. 47.

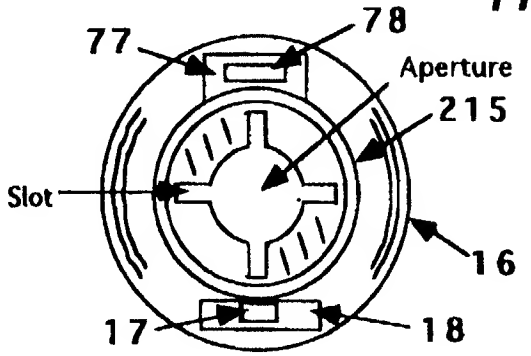

FIG. 48B.

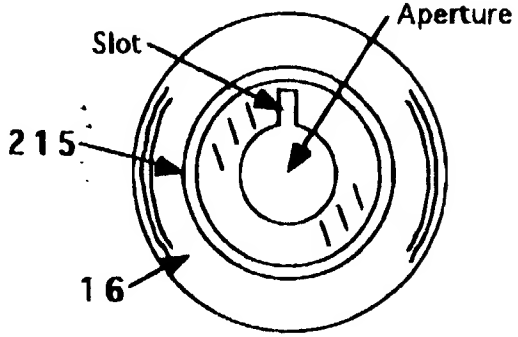

FIG. 48C.

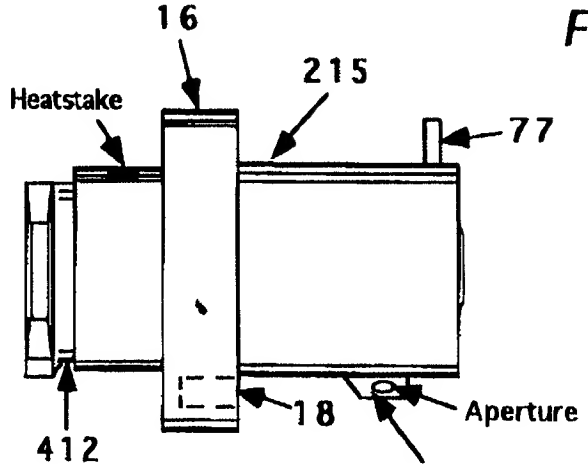

FIG. 48A

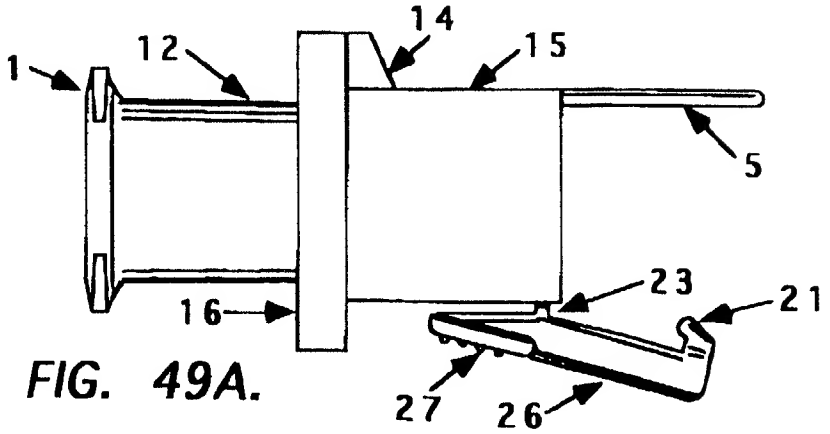

FIG. 49A.

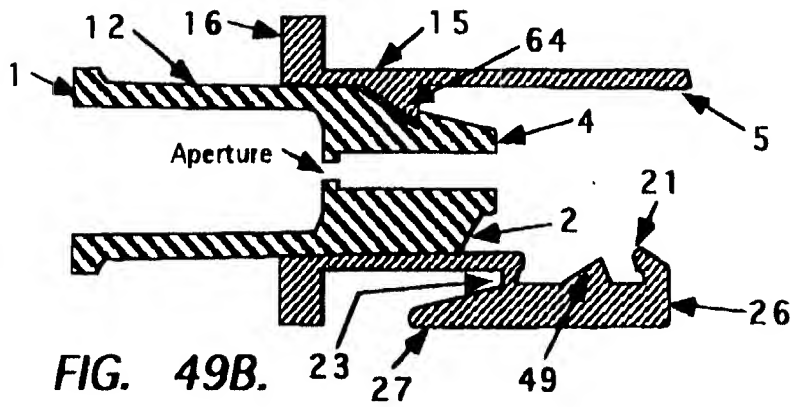

FIG. 49B.

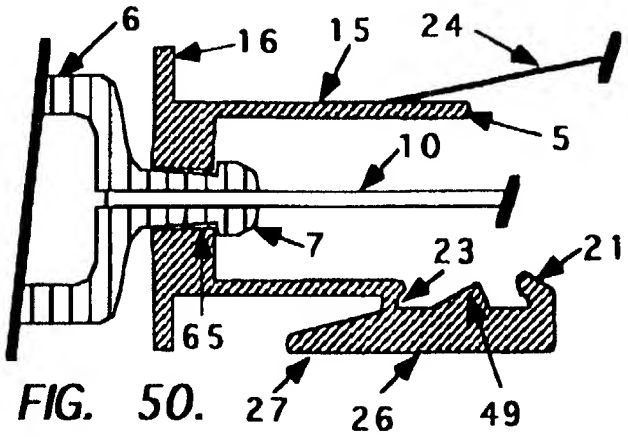

FIG. 50.

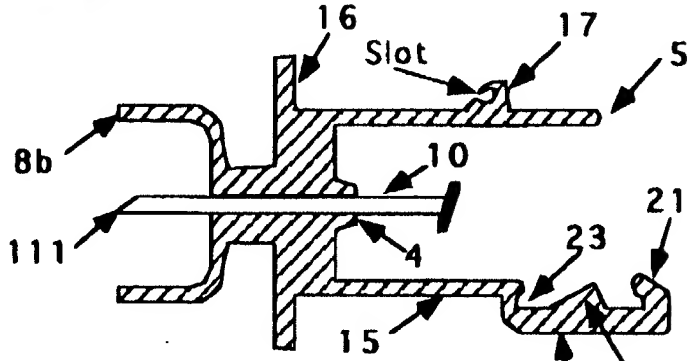

FIG. 52.

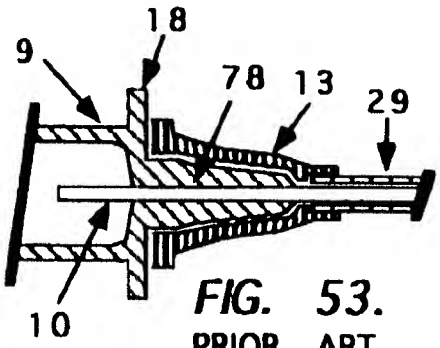

FIG. 53.
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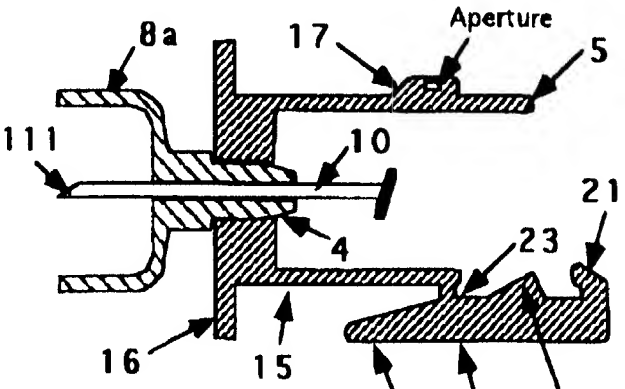

FIG. 51.

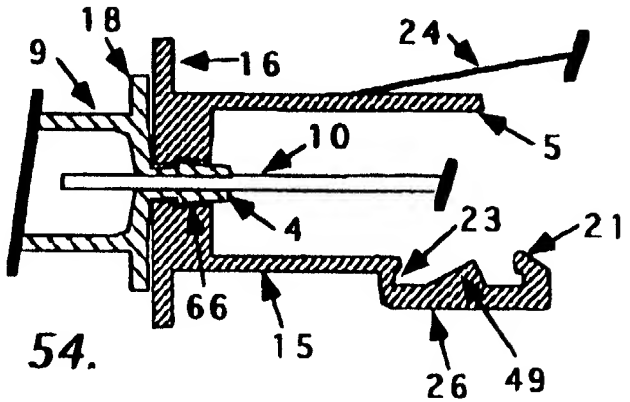

FIG. 54.

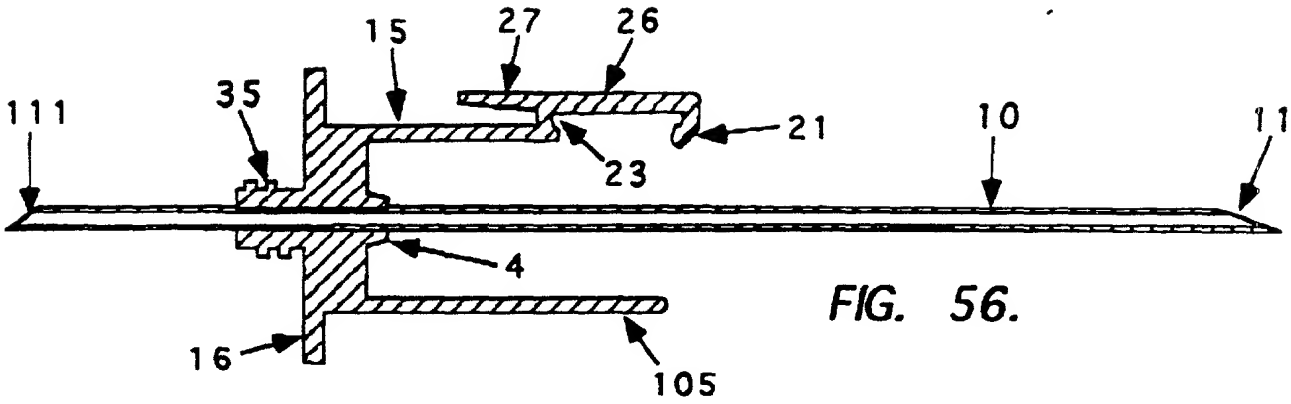

FIG. 56.

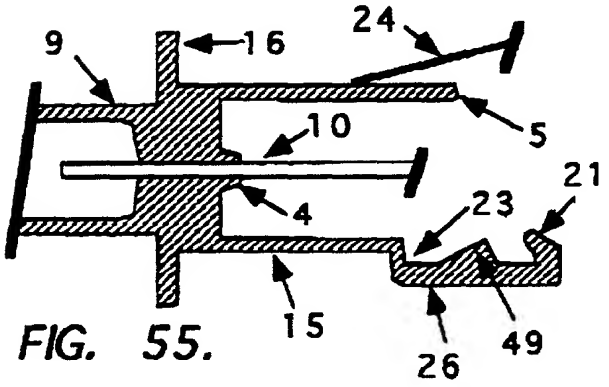

FIG. 55.

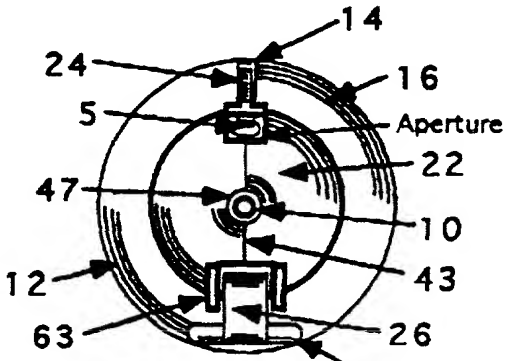

FIG. 57.

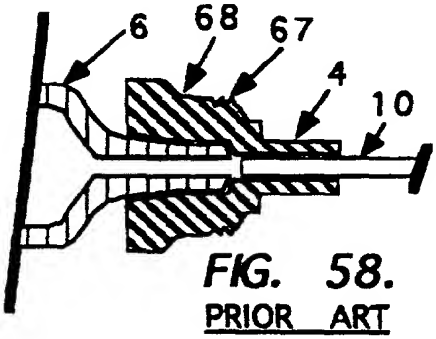

FIG. 58.
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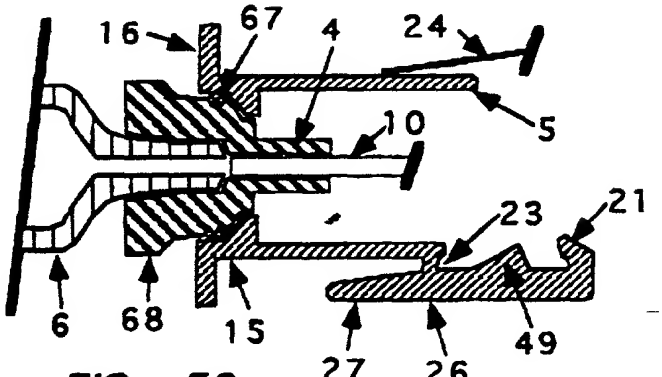


FIG. 59.

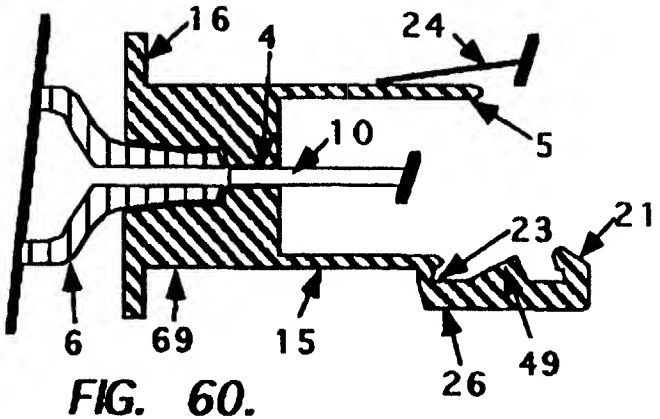


FIG. 60.

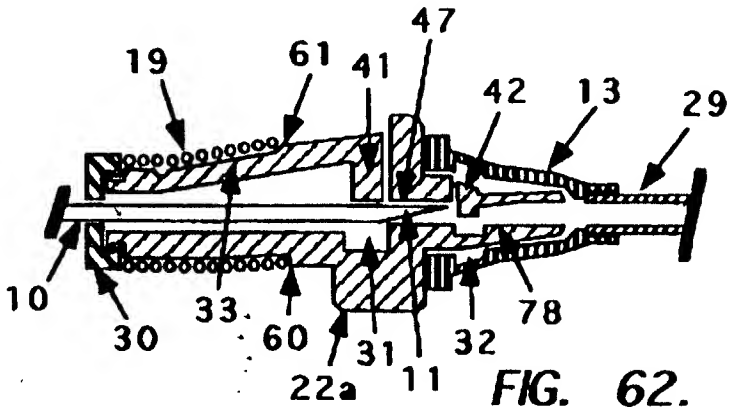


FIG. 62.

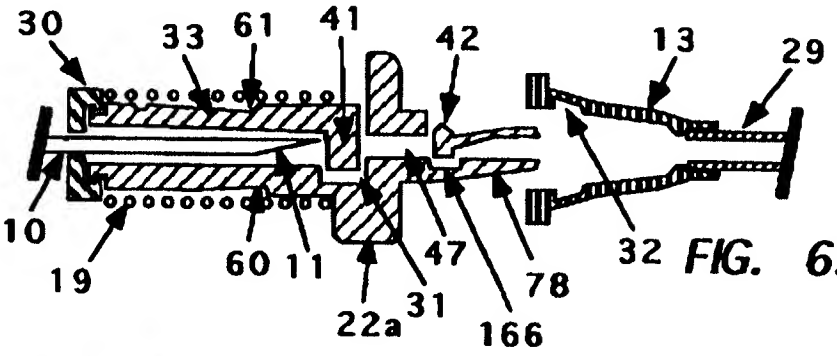


FIG. 63.

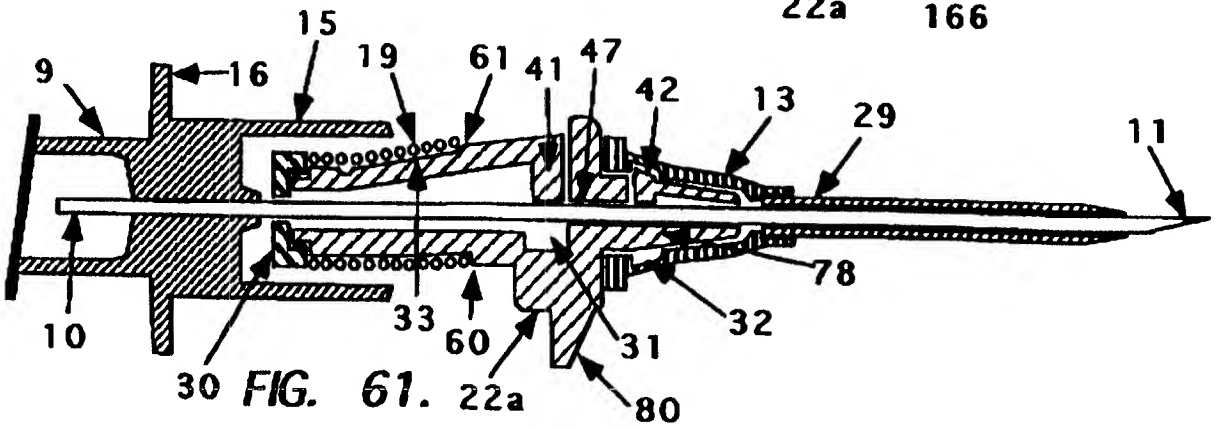


FIG. 61.

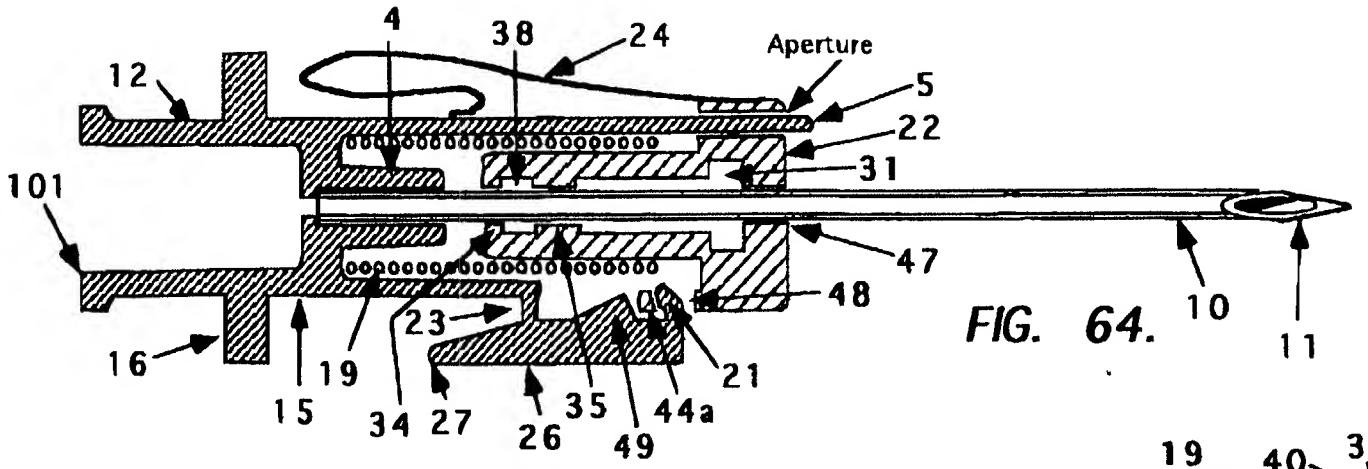


FIG. 64.

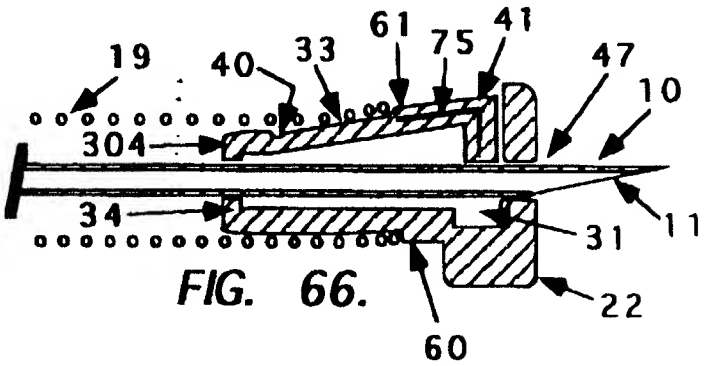


FIG. 66.

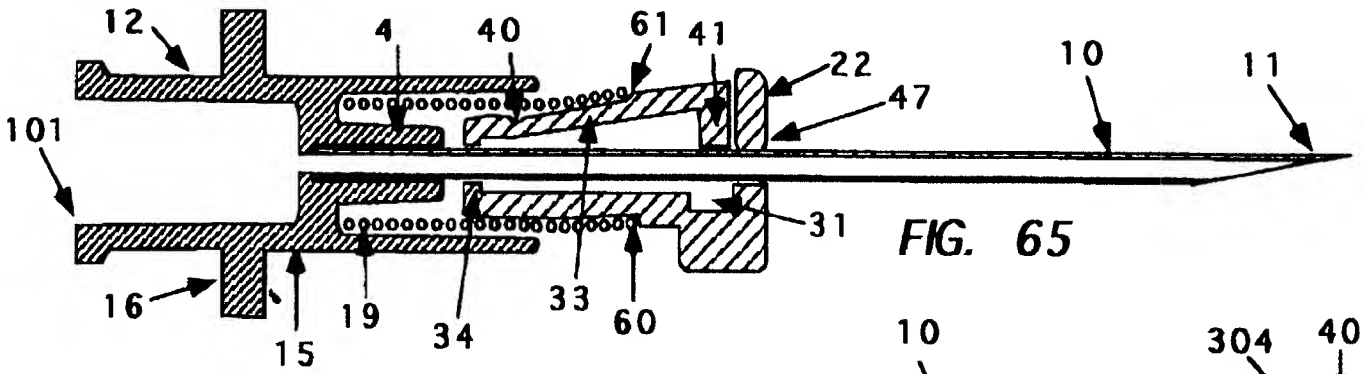


FIG. 65

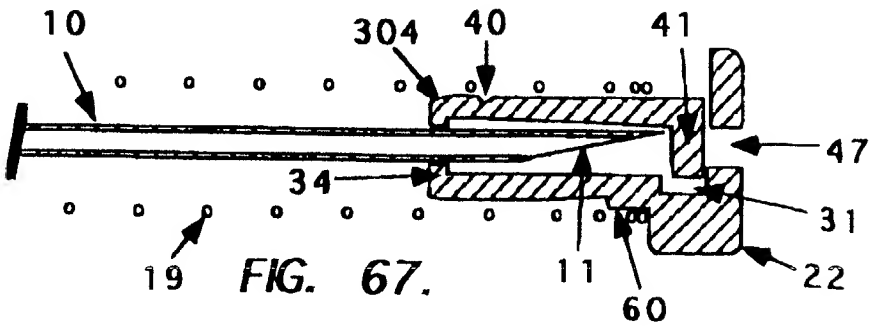


FIG. 67.

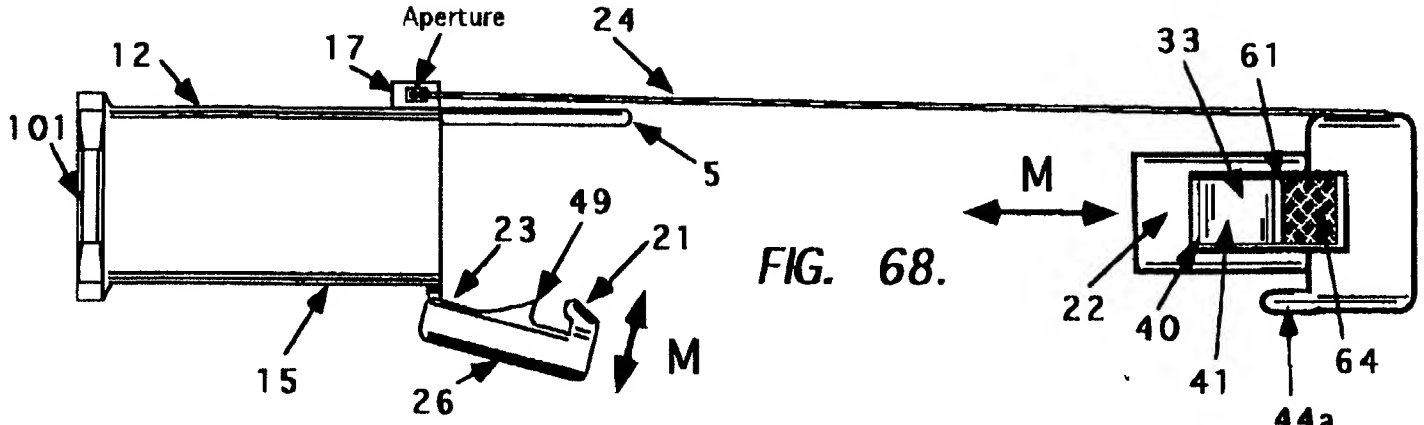


FIG. 68.

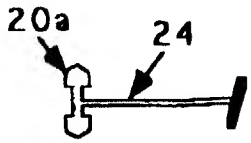


FIG. 70.

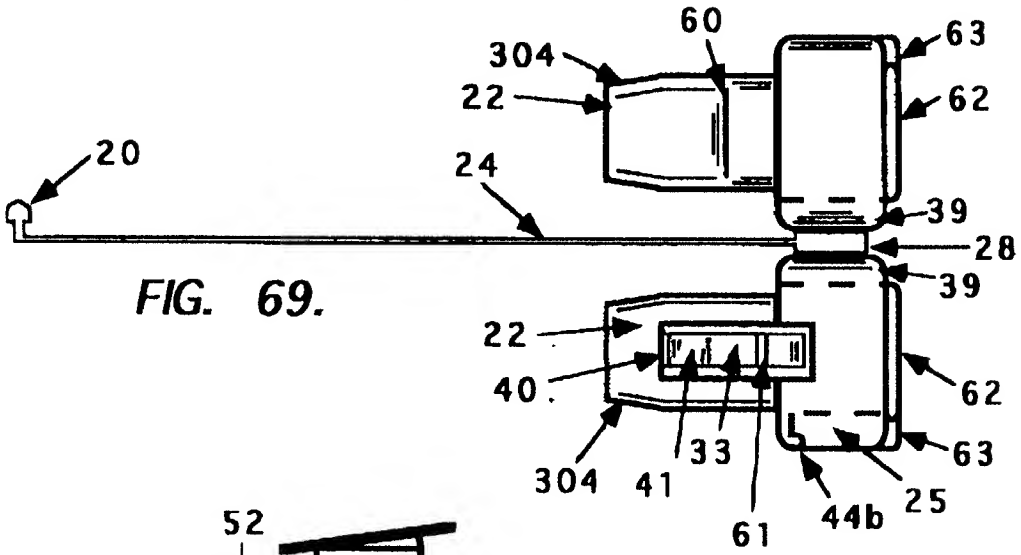


FIG. 69.

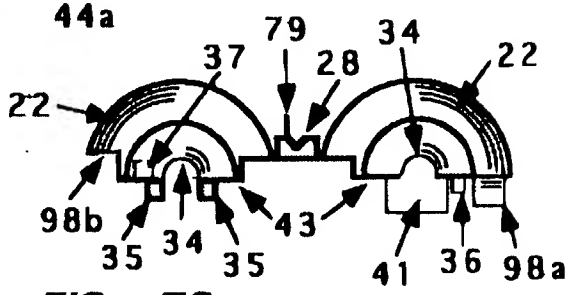


FIG. 73.

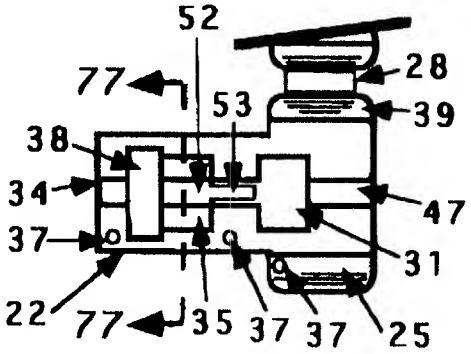


FIG. 74.

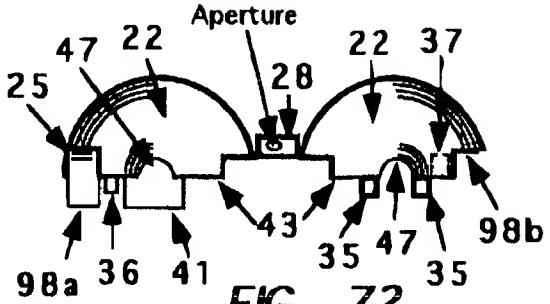


FIG. 72.

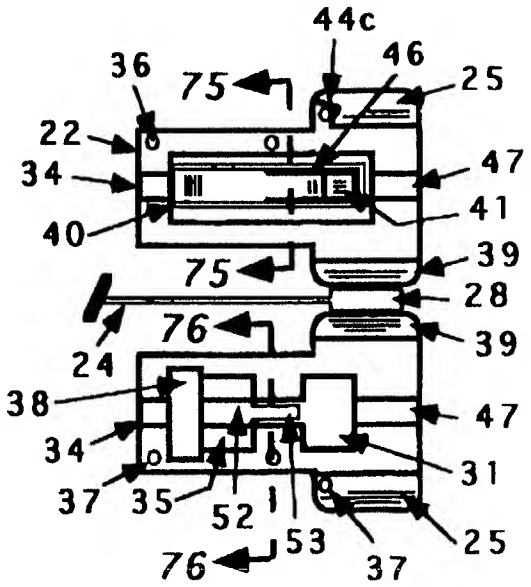


FIG. 71.

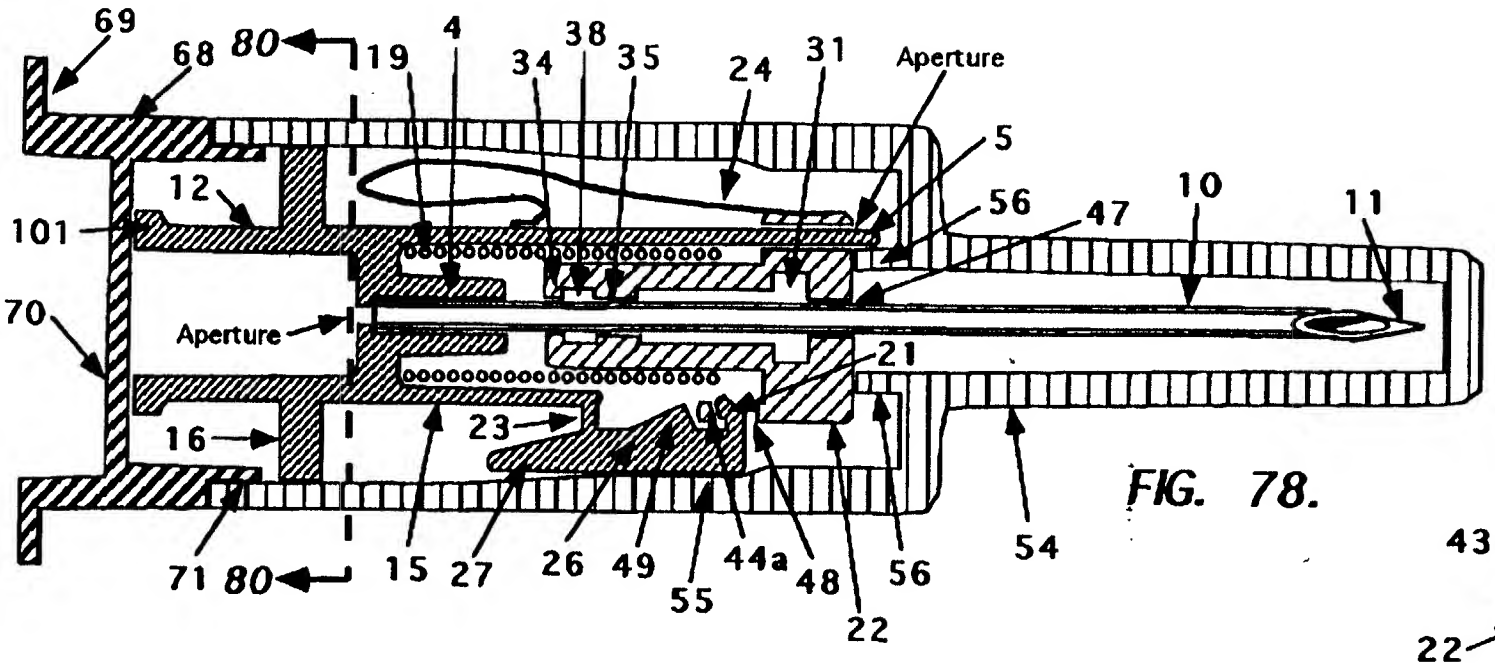


FIG. 78.

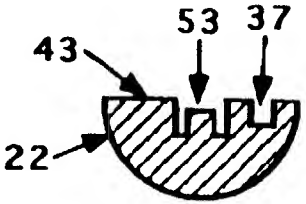


FIG. 76.

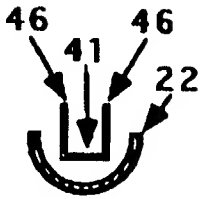


FIG. 75.

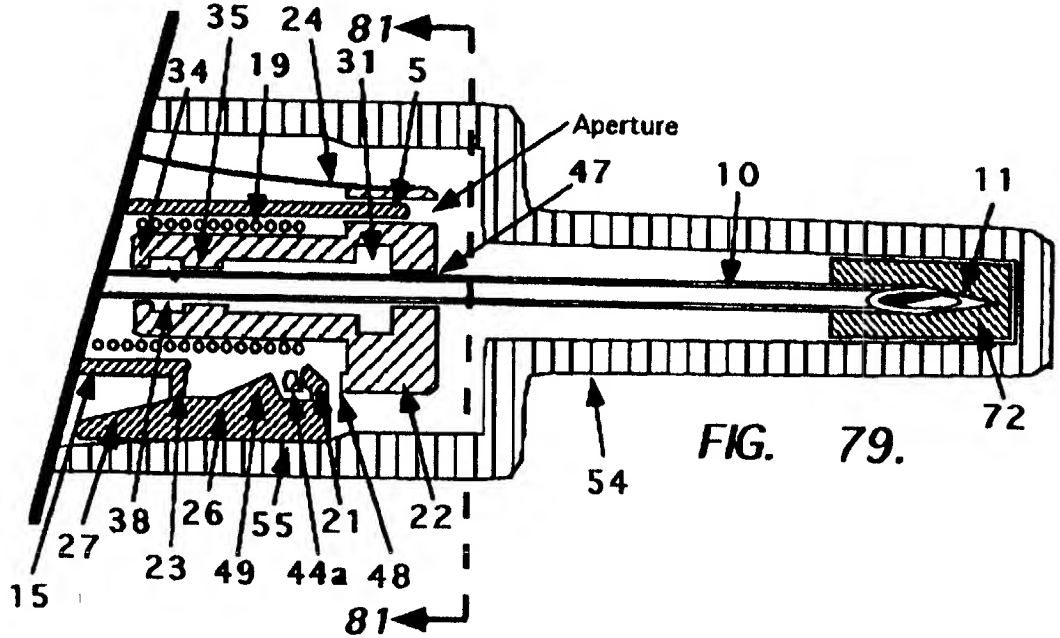


FIG. 79.

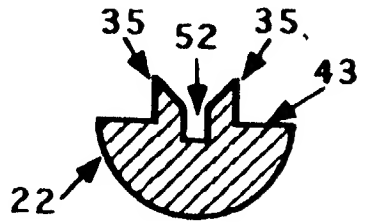


FIG. 77.

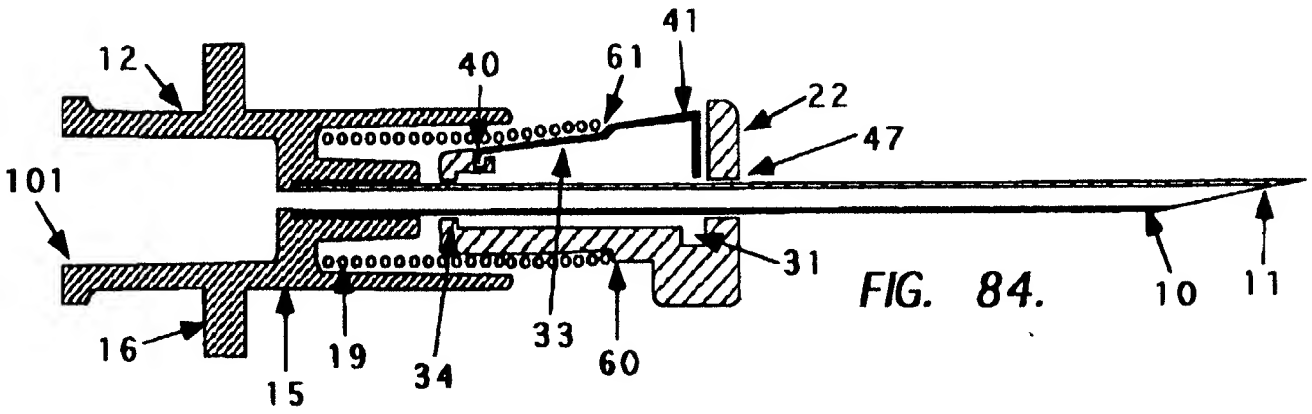


FIG. 84.

FIG. 83.

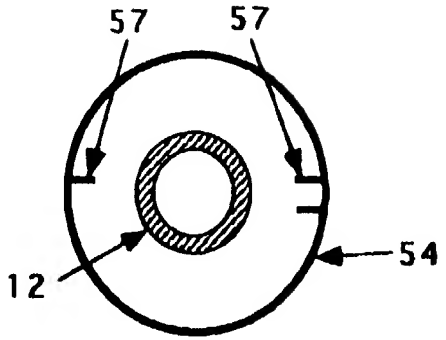


FIG. 80.

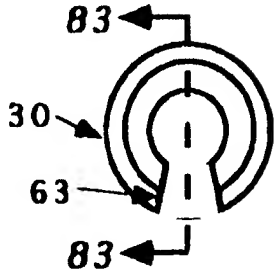


FIG. 82.

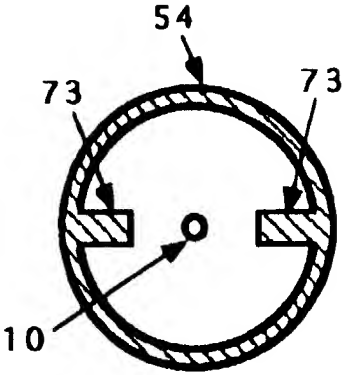


FIG. 81.

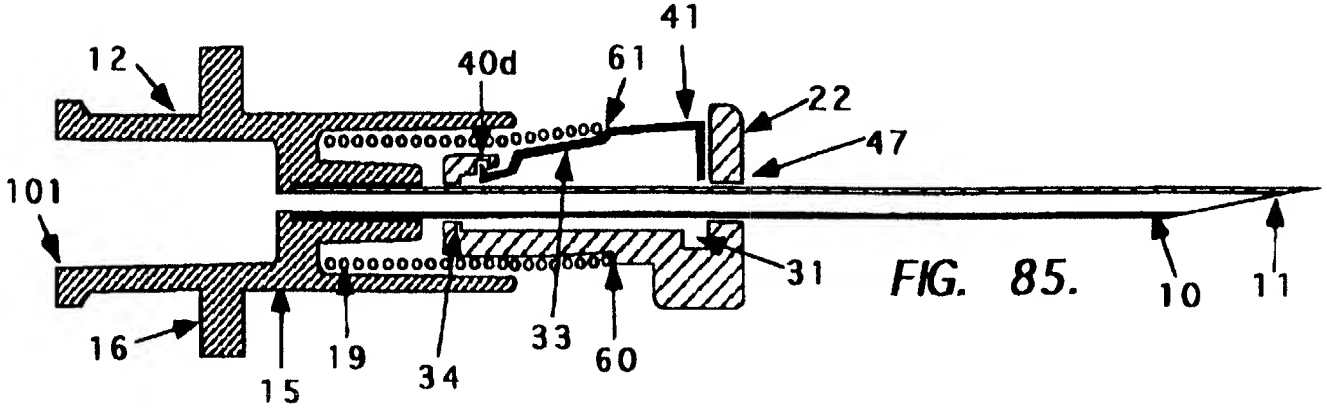
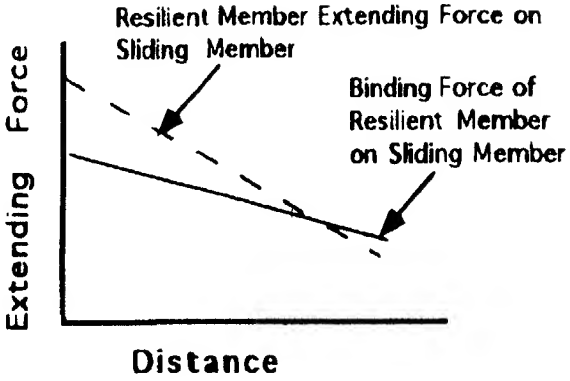
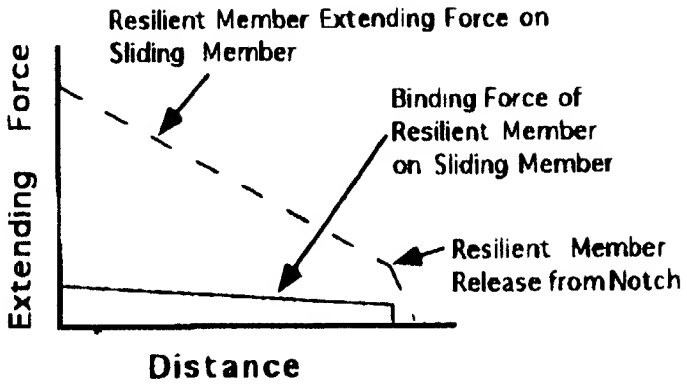


FIG. 85.



Resilient Member Extending Force On Sliding Member 22 **Without** Notch 60

FIG. 86.



Resilient Member Extending Force On Sliding Member 22 **With** Notch 60

FIG. 87.

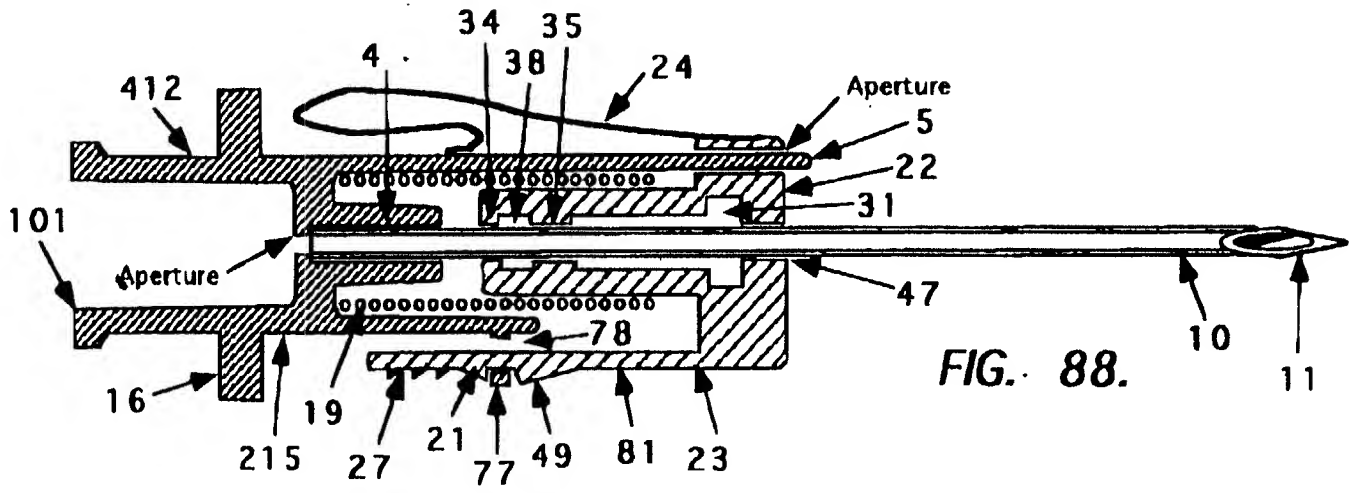


FIG. 88.

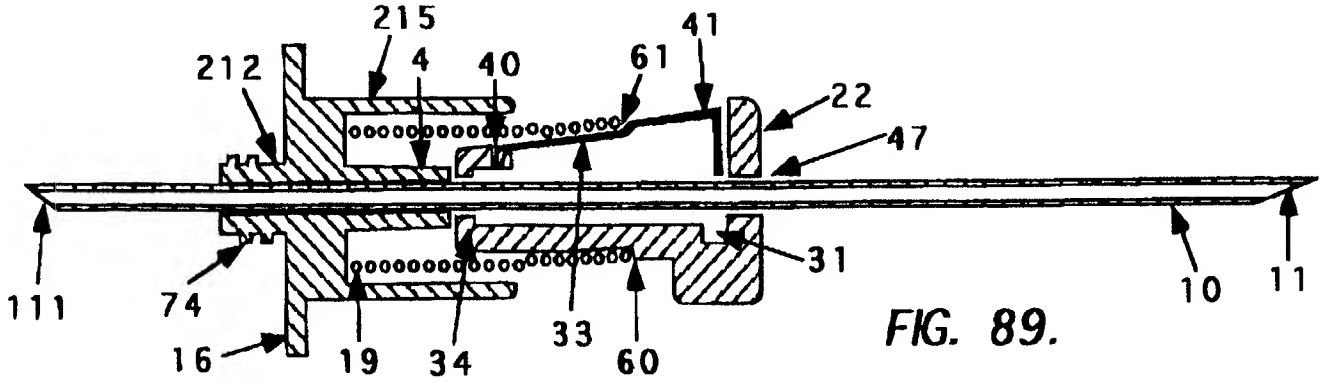


FIG. 89.

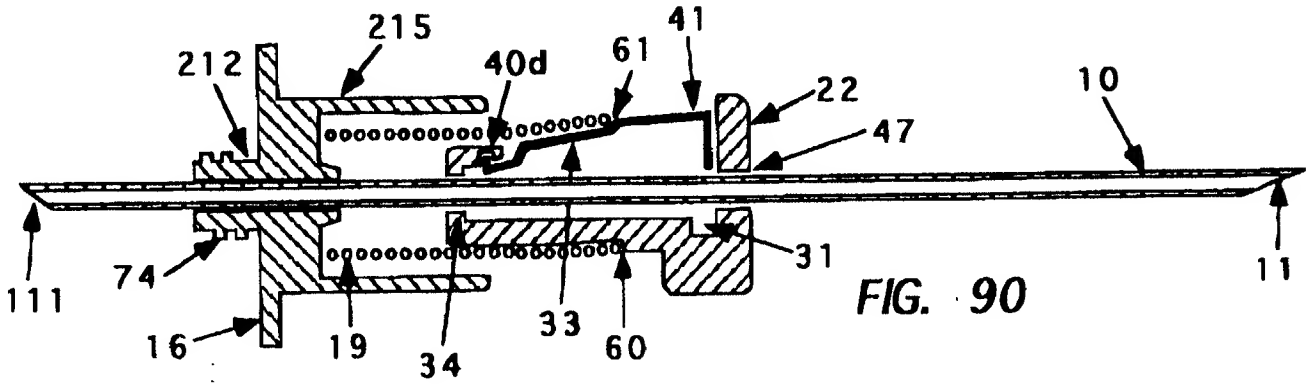


FIG. 90

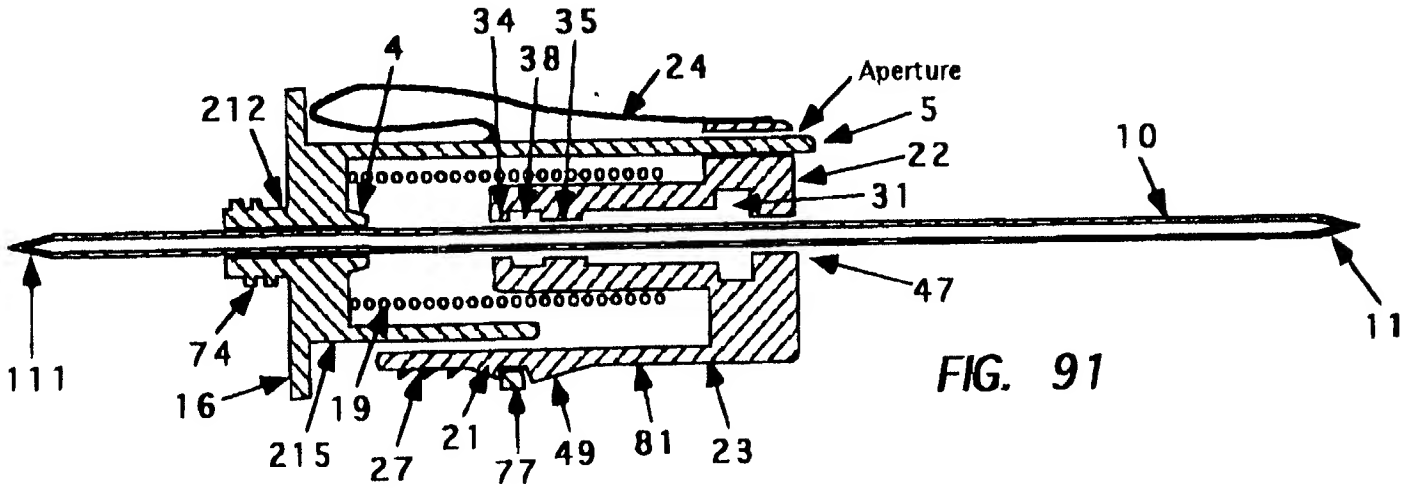


FIG. 91

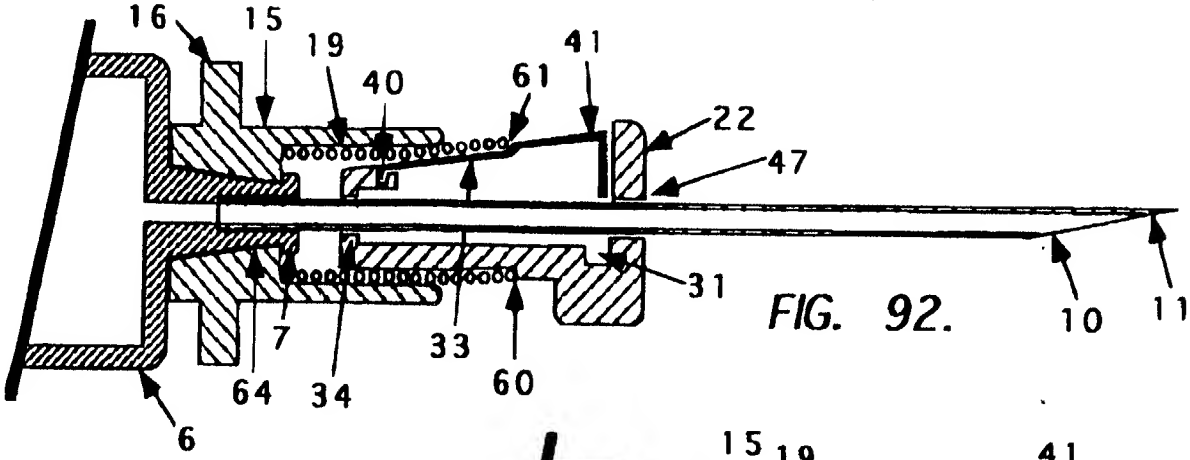


FIG. 92.

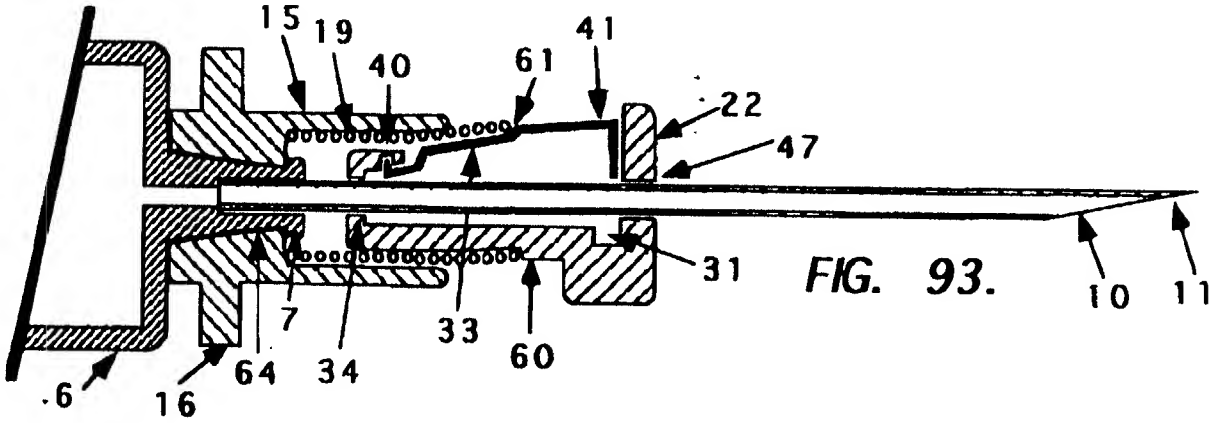


FIG. 93.

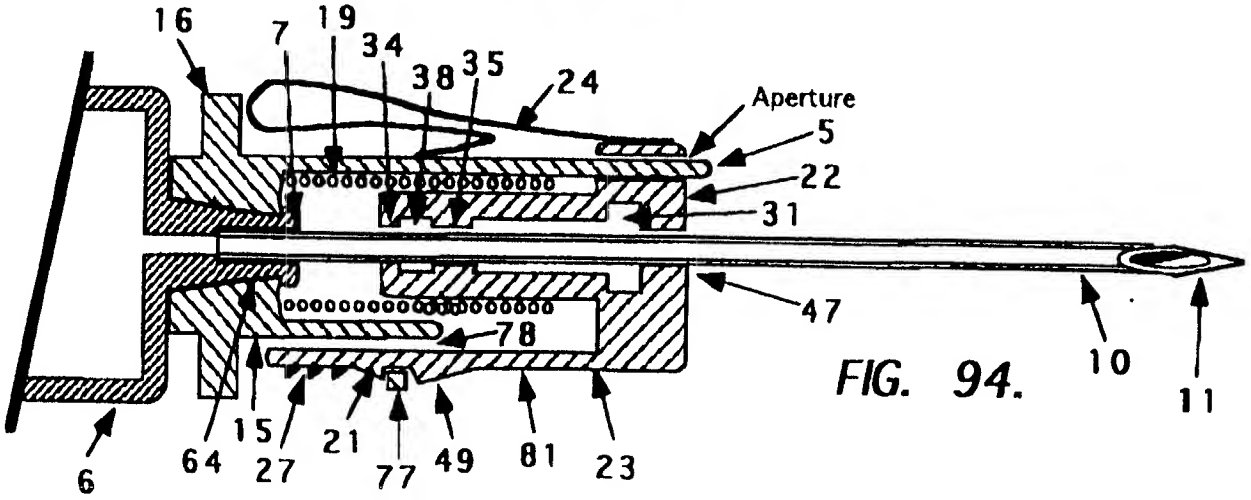


FIG. 94.

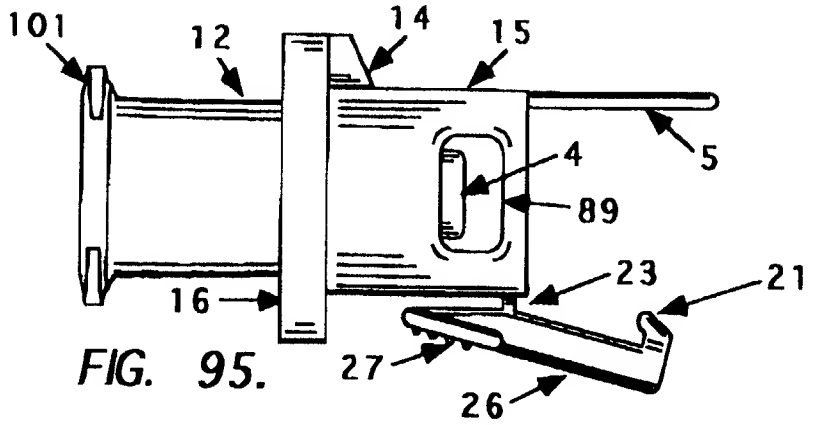


FIG. 95.

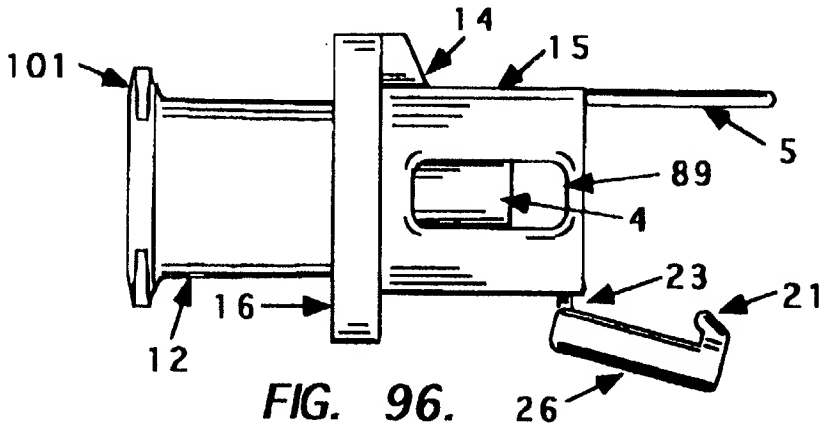


FIG. 96.

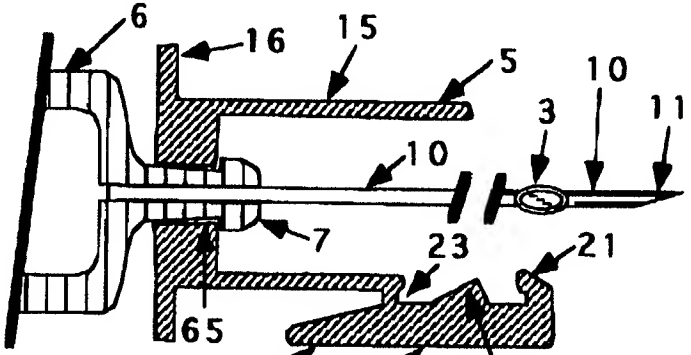


FIG. 97.

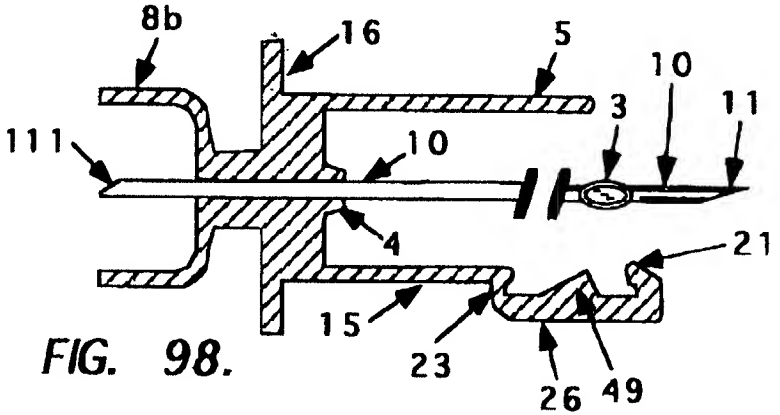


FIG. 98.

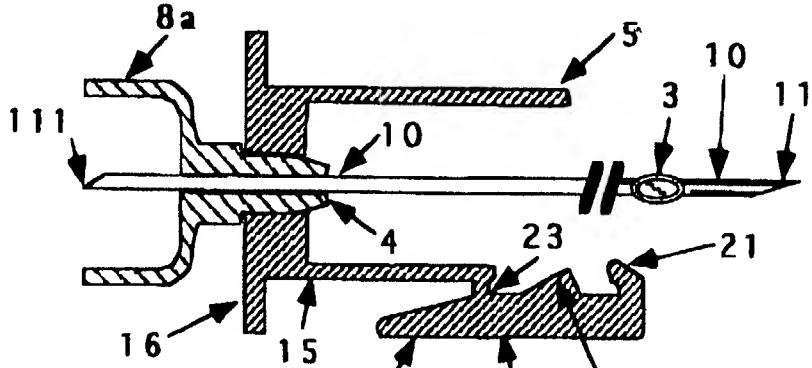


FIG. 99.

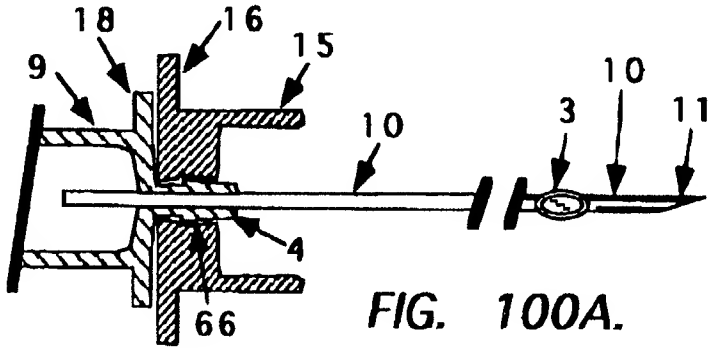


FIG. 100A.

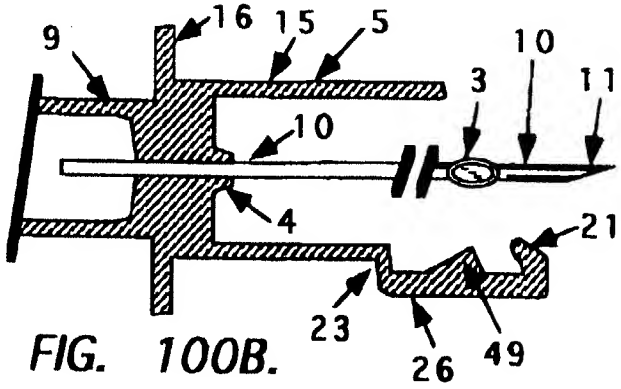


FIG. 100B.

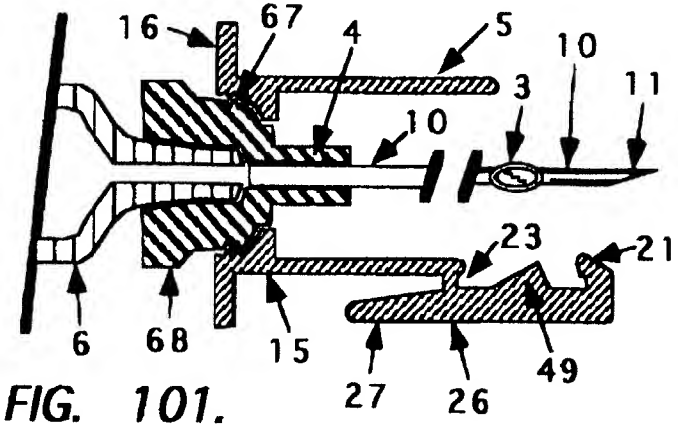


FIG. 101.

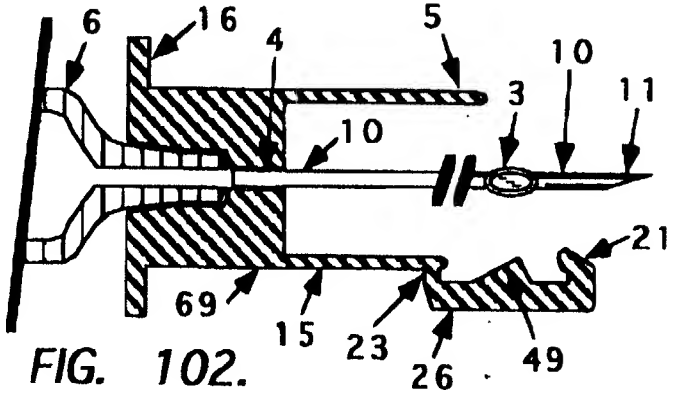


FIG. 102.

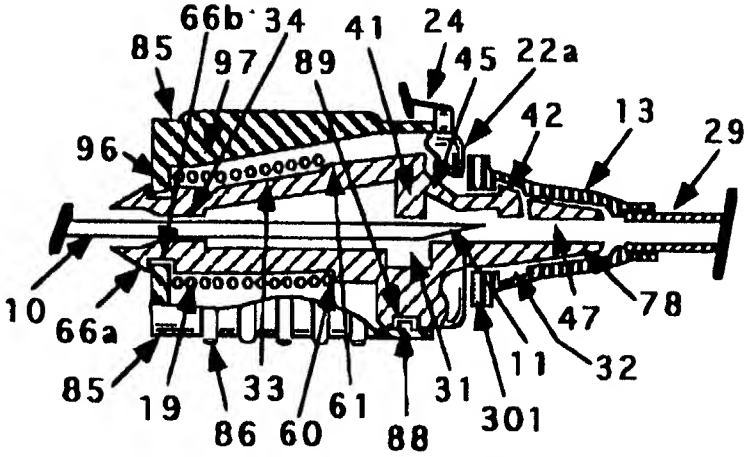


FIG. 104.

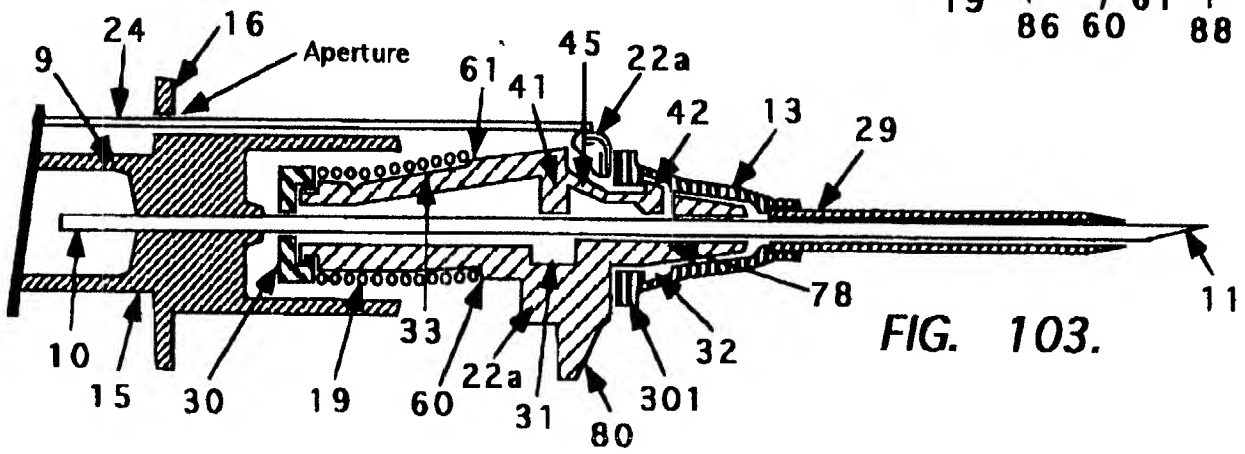


FIG. 103.

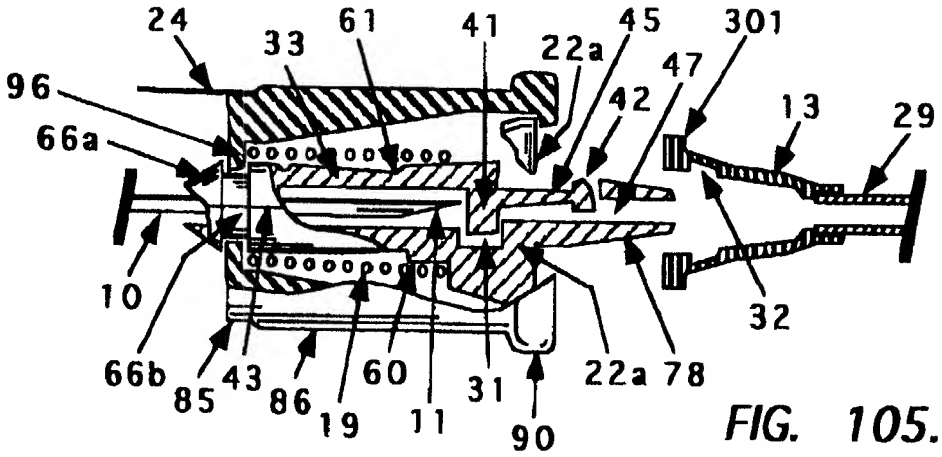


FIG. 105.

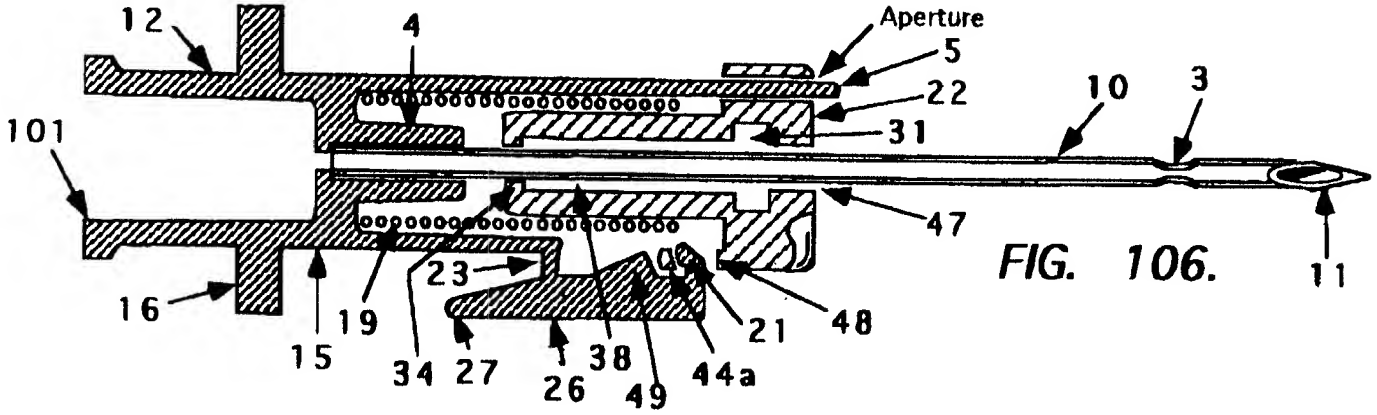


FIG. 106.

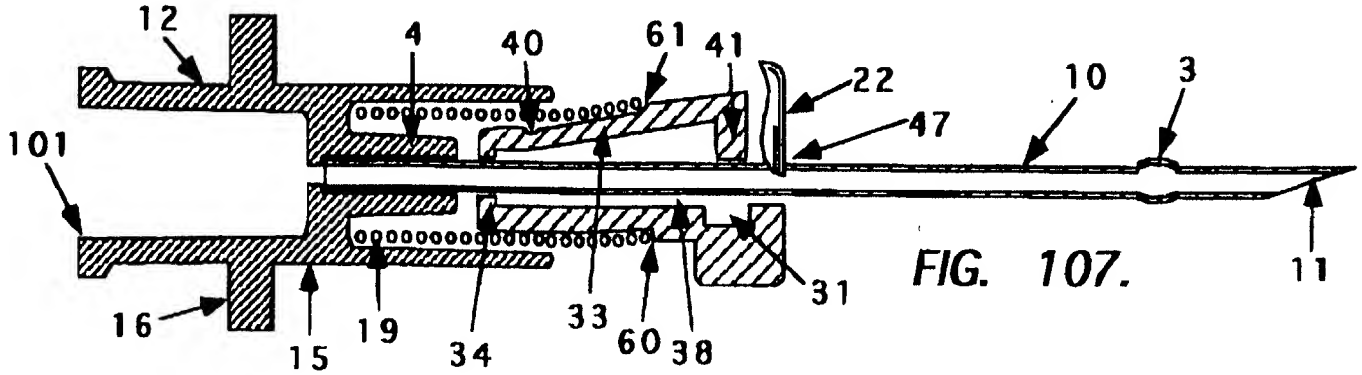


FIG. 107.

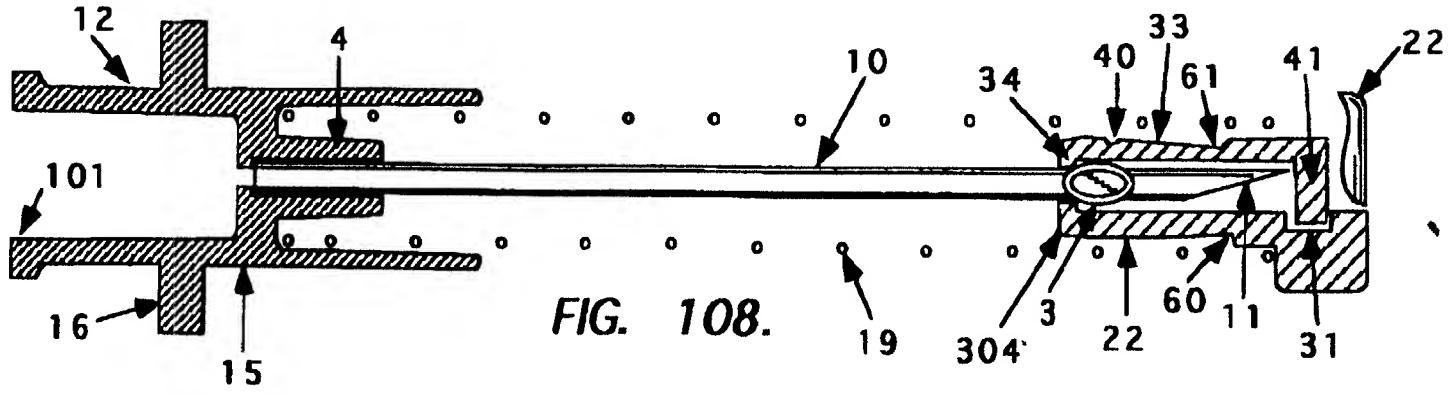


FIG. 108.

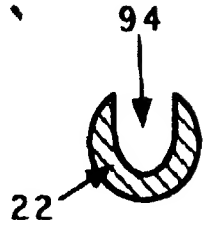


FIG. 111.

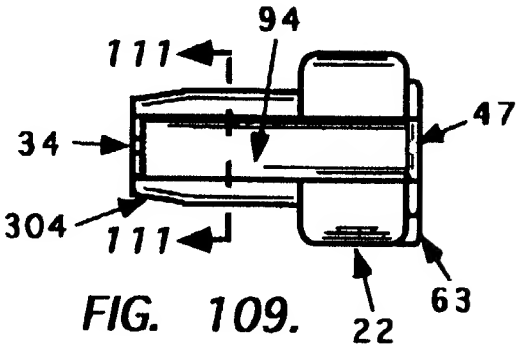


FIG. 109.

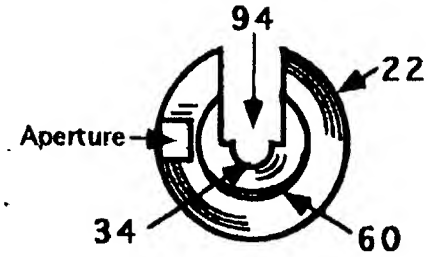


FIG. 113.

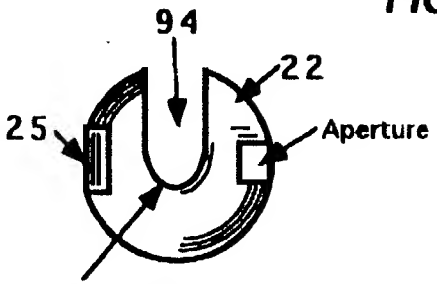


FIG. 110.

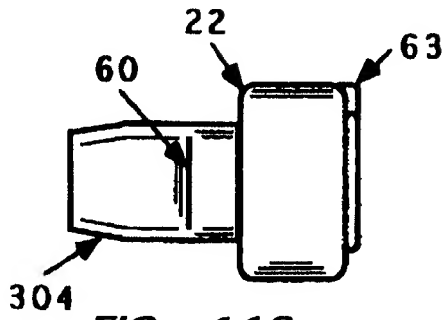


FIG. 112.

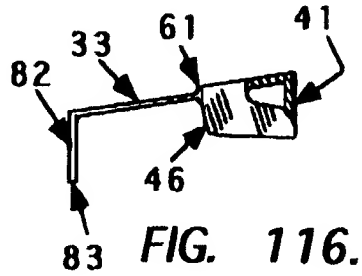


FIG. 116.

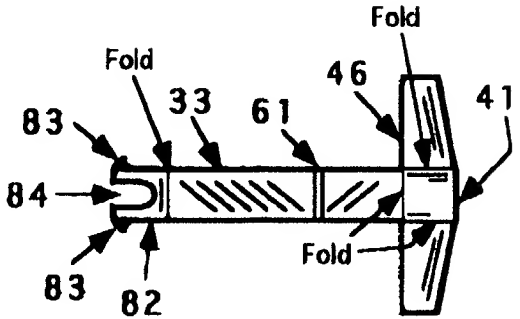


FIG. 119.

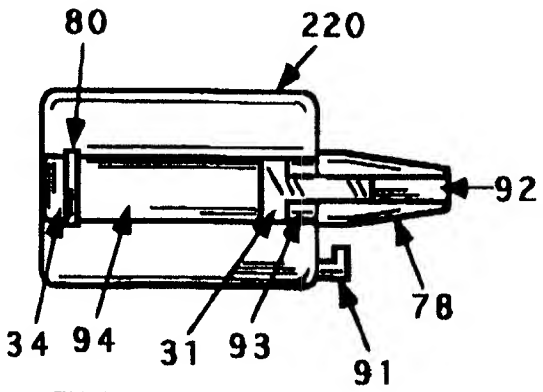


FIG. 114.

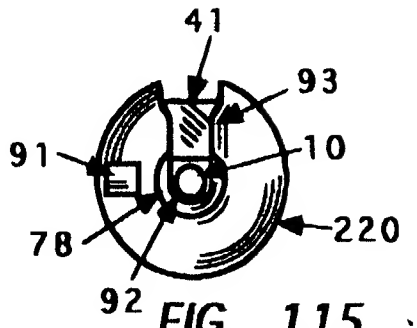


FIG. 115.

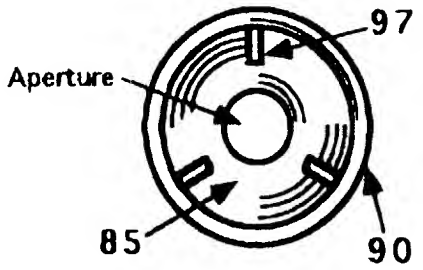


FIG. 117.

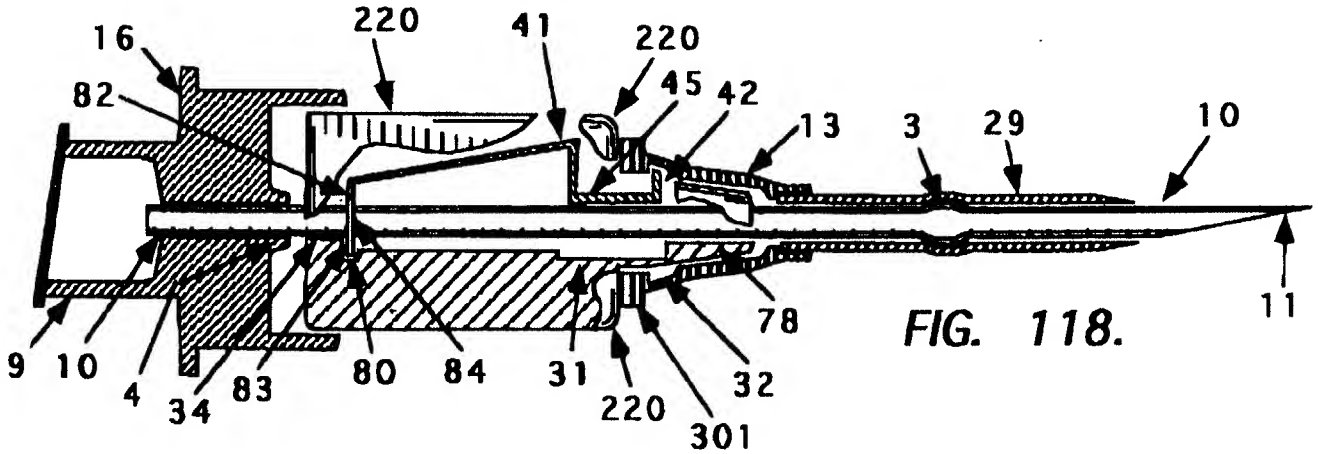


FIG. 118.

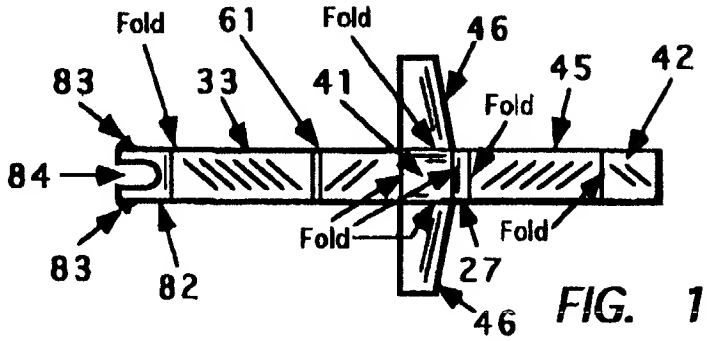


FIG. 123.

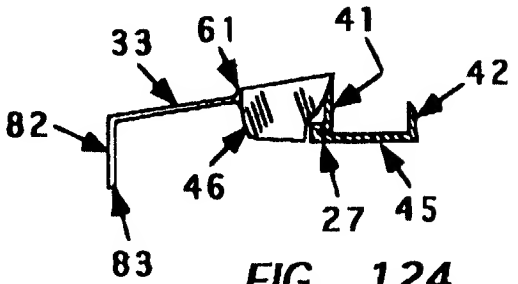


FIG. 124.

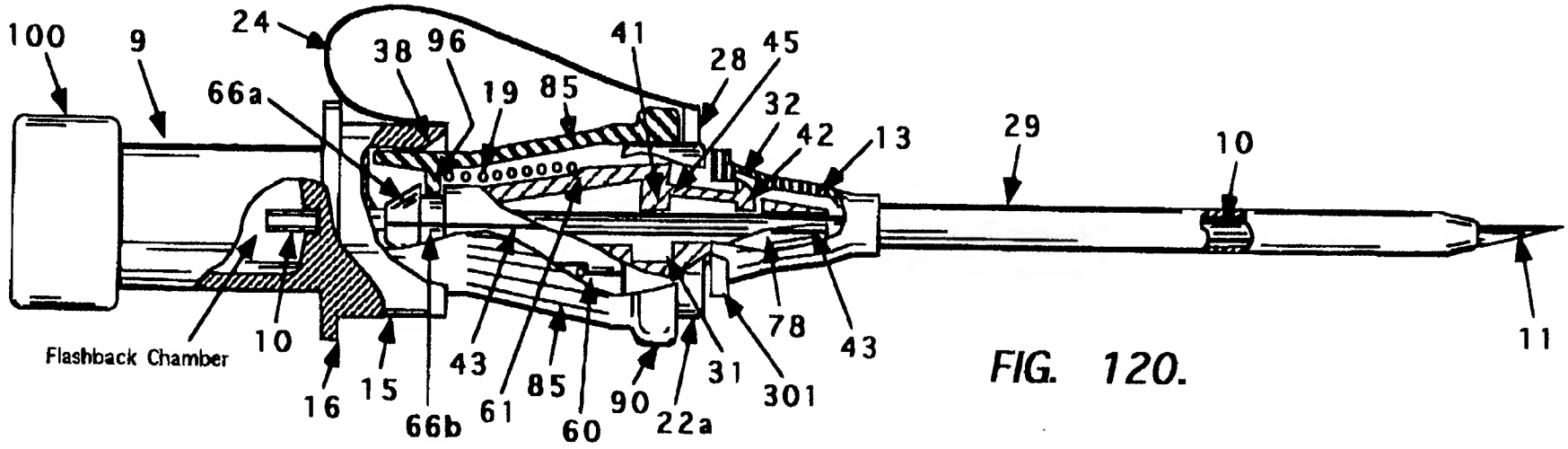


FIG. 120.

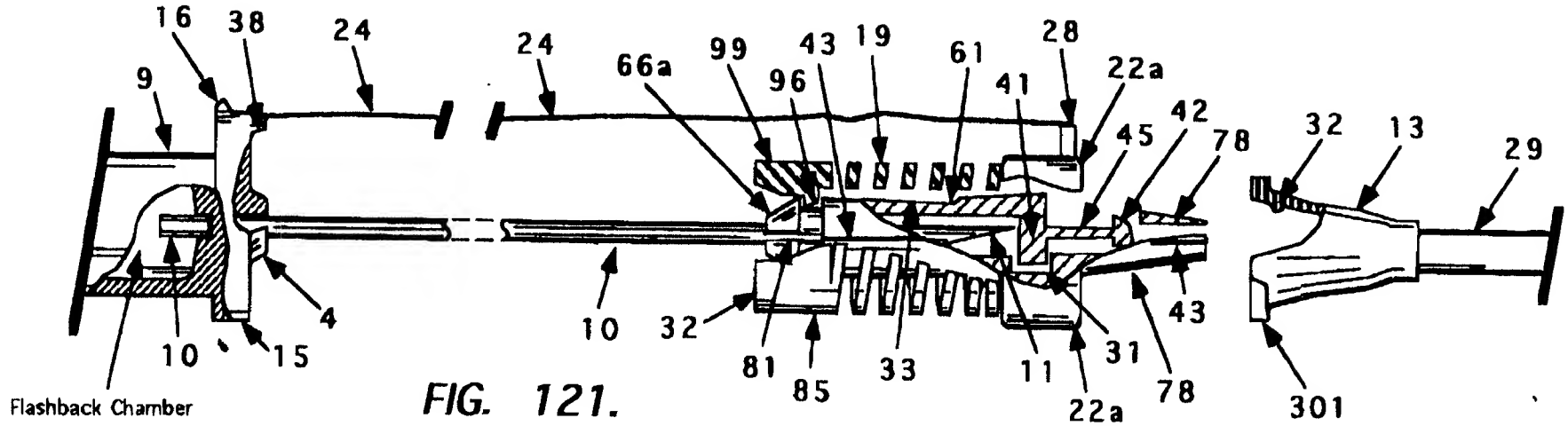


FIG. 121.

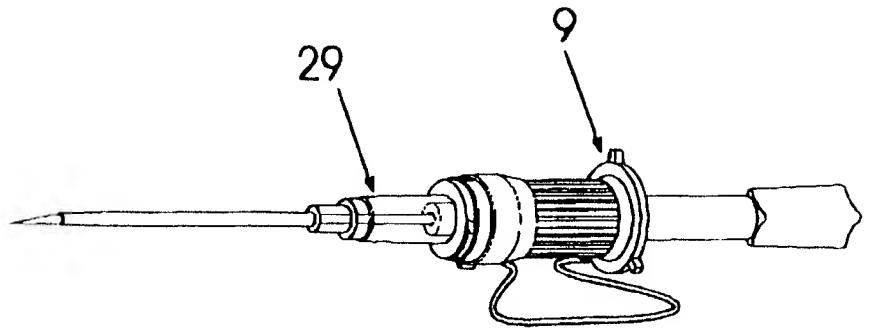


FIG. 122A

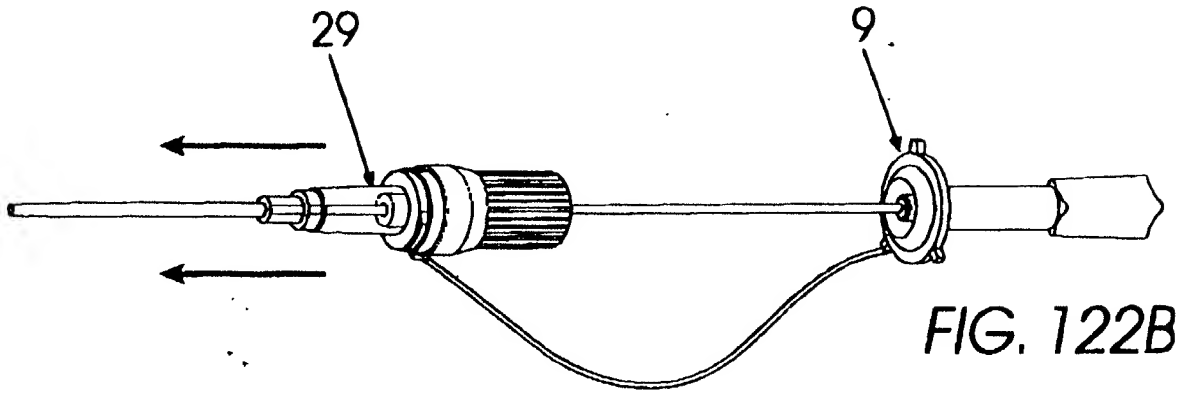


FIG. 122B

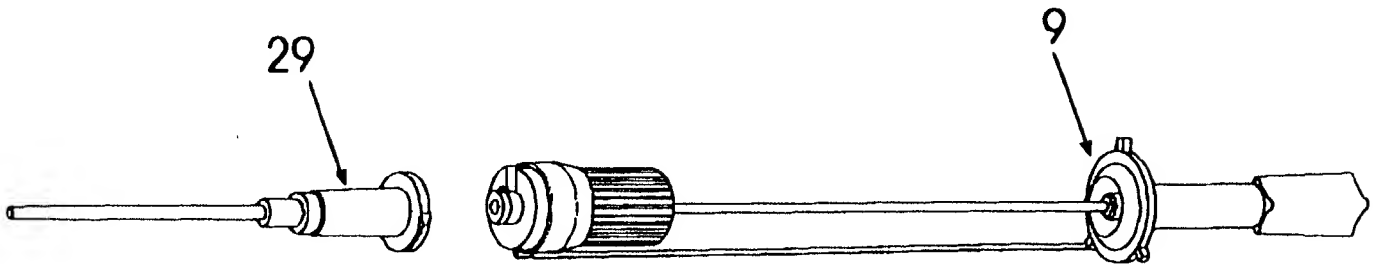


FIG. 122C

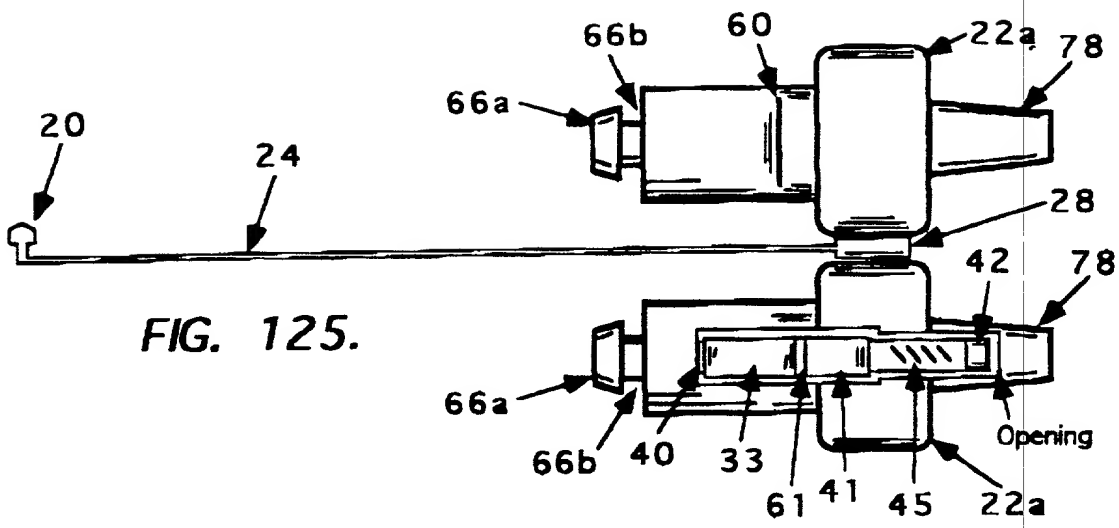


FIG. 125.

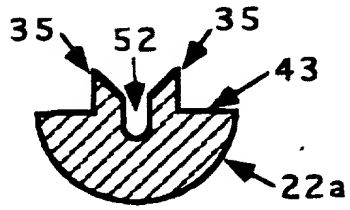


FIG. 129.

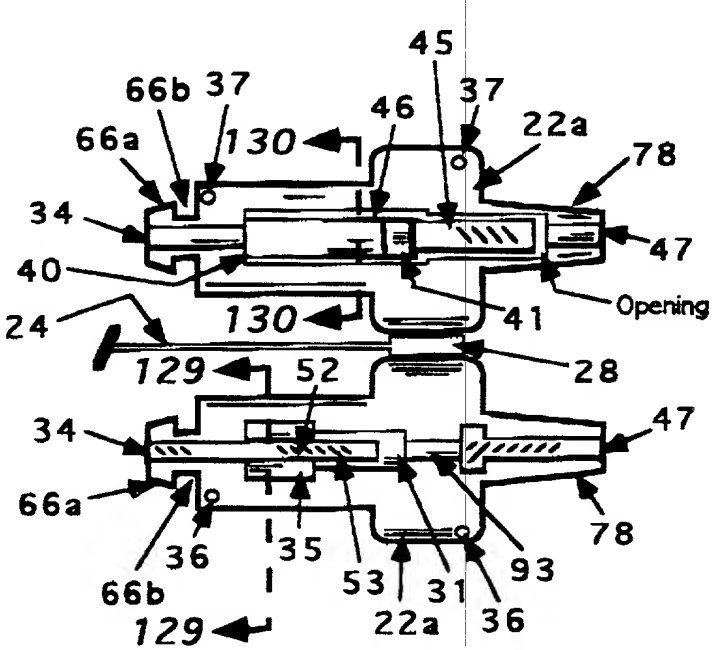


FIG. 126.

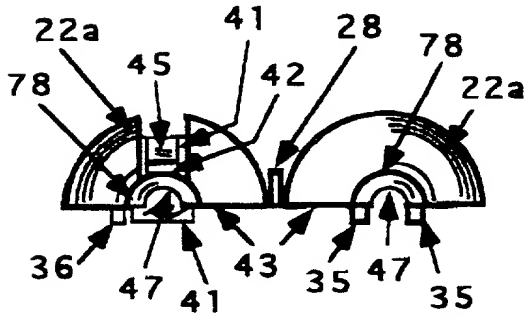


FIG. 127.

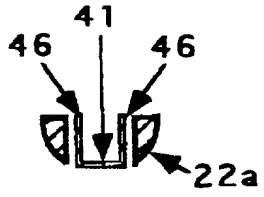


FIG. 130.

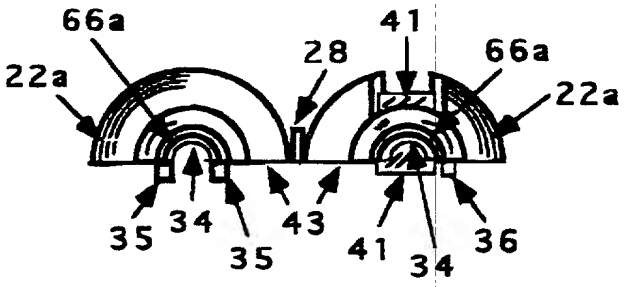


FIG. 128.

Attorney's Docket No.: 02933.P001 Patent

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name.

I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

NEEDLE TIP GUARD FOR HYPODERMIC NEEDLES

the specification of which

_____ is attached hereto.
XXX was filed on February 27, 1997 as
United States Application Number 08/807,328
or PCT International Application Number _____
and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above. I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to this application, and that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

			Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
(Number)	(Country)	(Day/Month/Year Filed)	Yes	No

I hereby claim the benefit under title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below

(Application Number)	Filing Date
60/012,343	27 February 1996
60/025,273	12 September1996
60/031,399	19 November 1996

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Number)	Filing Date	(Status -- patented, pending, abandoned)

I hereby appoint Aloysius T. C. AuYeung, Reg. No. 35,432; William Thomas Babbitt, Reg. No. 39,591; Jordan Michael Becker, Reg. No. 39,602; Bradley J. Bereznak, Reg. No. 33,474; Michael A. Bernadicou, Reg. No. 35,934; Roger W. Blakely, Jr., Reg. No. 25,831; Gregory D. Caldwell, Reg. No. 39,926; Kent M. Chen, Reg. No. 39,630; Lawrence M. Cho, Reg. No. 39,942; Thomas M. Coester, Reg. No. 39,637; Roland B. Cortes, Reg. No. 39,152; William Donald Davis, Reg. No. 38,428; Michael Anthony DeSanctis, Reg. No. 39,957; Daniel M. De Vos, Reg. No. 37,813; Karen L. Feisthamel, Reg. No. 40,264; James Y. Go, Reg. No. P-40,621; Tarek N. Fahmi, Reg. No. P-41,402; David R. Halvorson, Reg. No. 33,395; Eric Ho, Reg. No. 39,711; George W Hoover II, Reg. No. 32,992; Eric S. Hyman, Reg. No. 30,139; Dag H. Johansen, Reg. No. 36,172; Stephen L. King, Reg. No. 19,180; Dolly M. Lee, Reg. No. 39,742; Michael J. Mallie, Reg. No. 36,591; Kimberley G. Nobles, Reg. No. 38,255; Ronald W. Reagin, Reg. No. 20,340; James H. Salter, Reg. No. 35,668; William W. Schaal, Reg. No. 39,018; James C. Scheller, Reg. No. 31,195; Charles E. Shemwell, Reg. No. 40,171; Maria McCormack Sobrino, Reg. No. 31,639; Stanley W. Sokoloff, Reg. No. 25,128; Allan T. Sponseller, Reg. No. 38,318; Steven R. Sponseller, Reg. No. 39,384; Edwin H. Taylor, Reg. No. 25,129; Lester J. Vincent, Reg. No. 31,460; John Patrick Ward, Reg. No. 40,216; Ben J. Yorks, Reg. No. 33,609; and Norman Zafman, Reg. No. 26,250; my attorneys; and Robert Andrew Diehl, Reg. No. P-40,992; Sharmini Nathan Green, Reg. No. P-41,410; Thomas A. Hassing, Reg. No. 36,159; Edwin A. Sloane, Reg. No. 34,728; and Judith A. Szepesi, Reg. No. 39,393; my patent agents, of BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP, with offices located at 12400 Wilshire Boulevard, 7th Floor, Los Angeles, California 90025, telephone (310) 207-3800, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature Thomas C. Kuracina Date 02 May 1997

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Inventor's Signature [signature] Date 5-2-97

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Inventor's Signature [signature] Date 5/2/97

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Full Name of Fourth/Joint Inventor Richard Cohen

Inventor's Signature [signature] Date 5/2/97

Residence Agoura Hills, California (City, State) Citizenship USA (Country)

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Agoura Hills, California 91301

Title 37, Code of Federal Regulations, Section 1.56
Duty to Disclose Information Material to Patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclosure information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclosure all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made or record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.